Implementation of a Lightweight Assessment Method for Medical Device Software

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Abstract

This paper outlines the development and implementation of Medi SPICE-Adept. Medi SPICE-Adept is a lightweight assessment method that has been designed for usage with the Medi SPICE software process assessment and improvement model which is currently being developed for the medical device industry. While the Medi SPICE model is detailed and comprehensive in its approach there is industry demand for a lightweight medical device process assessment and improvement method. To address this requirement Medi SPICE-Adept has been developed. Details on how this has taken place and the procedures for implementing a Medi SPICE-Adept assessment are presented. Information is also provided regarding how a Medi SPICE-Adept assessment was undertaken in an Irish based medical device company. A summary of the issues identified from this assessment and the actions taken to facilitate process improvement is also presented. Finally, plans for future work are discussed.

Keywords

Medical Device Software, Software Process Improvement, SPI, Lightweight Process Assessment Method, Medical Device Software Process Assessment and Improvement.

1 Introduction

Due to the potential threat that medical devices can pose to patients, clinicians and third parties their development is highly regulated. In recent years there has been a significant increase in the role and importance that software plays in the healthcare industry [1]. The outcome of this has been the functionality, complexity and size of software components in medical devices has

substantially increased [2]. This development has been recognized by the European Union (EU) in their latest amendment to the Medical Device Directive (MDD) (2007/47/EC) [3]. As a result standalone software can now be classified as an active medical device in its own right in the EU. Given the importance and relevance of this measure the European Commission released a guidance document for the qualification and classification of standalone medical device software MEDDEV 2.1/ [4] in January 2012. In the United States (US) the Food and Drug Administration (FDA) is responsible for the regulation and approval of medical devices and has published software specific guidance documents for medical device software developers. These are the General Principals of Software Validation [5], Off the Shelf Software Use in Medical Devices [6] and Guidance on the Content of Premarket Submissions for Software Contained in Medical Devices [7]. To address the increasingly important role that software now plays the FDA recently published the Medical Device Data Systems Final Rule [8] and Draft Guidance in Relation to Mobile Applications [9].

Given the mission critical nature of medical device software compliance with the relevant regulations, and international standards of the location where a medical device is to be marketed is obligatory [10]. In the EU the receipt of the CE mark is essential and in the US FDA approval is required. There are approval bodies performing similar roles in other countries including China, Canada, India, Japan, and Australia. A key international standard for achieving regulatory compliance is IEC 62304:2006 [11] and its aligned standards ISO13485:2003 [12], ISO 14971:2007 [13], EN 60601-4:2000 [14], IEC 62366:2007 [15], and IEC 60812:2006 [16]. Information is also provided in the technical report IEC/TR 80002-1:2009 [17] and IEC 61508:2010 [18]. Despite the provision of these international standards, regulations and guidance documents the information they offer is high-level and no specific methods for performing the essential activities required have been provided [19].

It is therefore not surprising given the importance that achieving regulatory approval plays that organisations developing medical device software have focused on achieving compliance rather than implementing efficient processes and undertaking process improvement [20]. Previously this was not a critical issue due to the limited proportion of software in medical devices and it was acceptable to take a compliance centric approach. This is no longer the case and there is now a particular requirement for highly effective and efficient software development processes to be in place. These processes need to be defined in a regulatory compliant manner and then adopted to produce the required deliverables in order to achieve approval [19]. To address this requirement Medi SPICE [21], a medical device software process assessment and improvement model is currently under development and is discussed in section 2. While there is a specific requirement for Medi SPICE which is a comprehensive and detailed model there is also industry demand for lightweight medical device software process assessment methods [22]. Medi SPICE-Adept has been developed to help address this requirement and this is discussed in section 3 along with the procedure for its implementation. Section 4 outlines how a Medi SPICE-Adept assessment was undertaken and provides a summary of the process improvement plan which was collaboratively developed based on the findings report. Section 5 provides a summary and context for future work based on this research.

2 Medi SPICE

Existing generic Software Process Improvement (SPI) models are available which include the Capability Maturity Model Integration (CMMI®) [23] and ISO 15504-5:2006 [24] (SPICE), but these were not developed to provide sufficient coverage of all of the necessary areas required to achieve medical device regulatory compliance [25]. To address the requirement for a medical device software process assessment and improvement model the Regulated Software Research Group (RSRG) at Dundalk Institute of Technology (DkIT) undertook extensive research in the area [19]. This resulted in work commencing on the development of Medi SPICE a medical device specific software process assessment and improvement model which is being developed in collaboration with the SPICE User Group. This approach is in line with that taken for the development of Automotive SPICE [26] which is a software process assessment and improvement model which is domain specific to the automotive industry.

Medi SPICE is based upon the latest version of ISO/IEC 15504-5 (currently under ballot) and ISO/IEC 12207:2008 [27]. It also provides coverage of the relevant medical device regulations, standards, technical reports and guidance documents. These include IEC 62304:2006 and its aligned standards, the FDA regulations [28] and guidance documents and the European MDD and guidelines. The objective of undertaking a Medi SPICE assessment is to determine the state of a medical device organisation's software processes and practices in relation to the regulatory requirements of the industry and to identify areas for process improvement [29]. It can also be used as part of the supplier selection process when an organisation wishes to outsource or offshore part or all of their medical device software development to a third party or remote division [30].

Medi SPICE contains a Process Reference Model (PRM) which consists of forty two processes and fifteen subprocesses which are fundamental to the development of regulatory compliant medical de-vice software. Each process has a clearly defined purpose and outcomes that must be accomplished to achieve that purpose. Medi SPICE also contains a Process Assessment Model (PAM) which is related to the PRM and forms the basis for collecting evidence and the rating of process capability. This is achieved by the provision of a two-dimensional view of process capability. In one dimension, it describes a set of process specific practices that allow the achievement of the process outcomes and purpose defined in the PRM; this is termed the process dimension. In the other dimension, the PAM describes capabilities that relate to the process capability levels and process attributes, this is termed the capability dimension.

In line with ISO/IEC 15504-2:2003 [31] Medi SPICE process capability is defined over 6 levels:

- Level 0 Incomplete;
- Level 1 Performed;

- Level 2 Managed;
- Level 3 Established;
- Level 4 Predictable;
- Level 5 Optimizing.

The Medi SPICE PRM and PAM are being released in stages and each stage is extensively reviewed by interested parties from the SPICE User Group, representatives from international standards bodies and industry experts. This collaborative approach is seen as a key element in the development of Medi SPICE to ensure coverage of both the SPI and medical device software regulatory requirements [29]. Medi SPICE is a comprehensive and detailed model and its overall objective is to provide a conformity assessment scheme to support first, second or third party assessments. It is envisaged that results from these assessments may be recognized by the relevant regulatory bodies.

3 Medi SPICE-Adept

As outlined in section two there is a specific requirement for a detailed and comprehensive process assessment and improvement model which is specific to the medical device domain which Medi SPICE is being developed to address. As with other SPI assessments models i.e. CMMI® and IEC 15504-5:2006 a full Medi SPICE assessment will require considerable planning and resources to successfully undertake. While Medi SPICE is being developed with the objective of being as efficient as possible the necessity for rigour dictates the level of planning, resources and analysis required for its successful implementation. While the need for and importance of Medi SPICE is understood [21], it was also appreciated by the RSRG that there is a specific requirement for lightweight assessment methods in the medical device software industry [32]. In particular there was industry led demand for a lightweight assessment method based on Medi SPICE. This was communicated directly to the RSRG by numerous medical device organisations. To address this specific requirement Medi SPICE-Adept was developed. There were two additional objectives in undertaking this task. The first was the opportunity to leverage the extensive research [19] and level of detail which developing Medi SPICE provided. The second was the opportunity to identify and facilitate the use of agile and lean methods for medical device software development. The use of agile and lean methods in this context is an area that the RSRG are also currently researching to assist organisations increase the efficiency of their software development practices [33].

To be effective Medi SPICE-Adept required the employment of a lightweight approach for undertaking software process assessment and improvement. This included the use of a limited number of personnel to carryout and participate in the assessment while also maximising the benefit of the time and effort of those involved. It was envisaged that Medi SPICE-Adept would eventually encompass all the Medi SPICE processes. It was therefore recognized that an assessment could take

place over a day or a number of days depending on how many processes were being assessed. It was also important that organisations could select the specific processes which were of most benefit for achieving their business goals. The focus of the method had to be on the evaluation of the essential practices, key work products and the achievement of the outcomes which were necessary for the attainment of the specific process purpose being assessed. Medi SPICE-Adept therefore needed to be process dimension centric in its focus. Finally the objective of undertaking a Medi SPICE-Adept assessment was not to receive formal certification or a rating, but rather to identify an organization's strengths and weaknesses and to facilitate process improvement. Having defined the criteria which had to be met the next step was to undertake the development of Medi SPICE-Adept.

3.1 Developing Medi SPICE-Adept

The RSRG having previously successfully developed and implemented three lightweight software process assessment methods Adept [34], Med-Adept [35] and Med-Trace [36] the objective was to leverage that experience and utilise it for the development of Medi SPICE-Adept. It was in this context that work commenced on the development of Medi SPICE-Adept. It was recognized that this assessment method needed to cover more processes and provide more detailed analysis than those methods which had been previously developed. While this was the case Medi SPICE-Adept was still required to be lightweight to fulfil its purpose. The first task was to identify the initial Medi SPICE processes that would be utilised. The goal was to select a limited number of processes that would be most beneficial and relevant to industry. To achieve this, industry experts were consulted and ten processes were selected:

- Requirements Elicitation;
- System Architectural design;
- Systems Requirements Analysis;
- Software Requirements Analysis,
- Software Construction;
- Software Integration;
- Software Testing;
- Configuration Management;
- Change Request Management;
- Verification.

While these were the initial processes selected Medi SPICE-Adept will provide coverage of all the Medi SPICE processes and subprocesses.

The Medi SPICE PAM had been developed for each of the initial processes which were based on best practice as outlined by the latest version of ISO/IEC 15504-5 and the specific requirements of the medical device regulations, standards, technical reports and guidance documents. As a result each process had a defined purpose and outcomes, specific practices and work products were also included for the achievement of these outcomes and purpose. In addition each outcome and specific practice was cross referenced to the regulations, standards etc. on which it was based. To facilitate the assessment each of the initial processes were evaluated and specific questions identified based on the Medi SPICE PAM. In addition questions on the current or potential use of agile and lean methods were also identified and included. This work was undertaken by five members of the RSRG team with extensive experience of SPI and knowledge of medical device software development and included two experts in the area of lean and agile methods. Having defined the assessment instrument the next step was to develop the specific procedure for undertaking a Medi SPICE-Adept assessment.

3.2 The Procedure for Undertaking a Medi SPICE-Adept Assessment

Based on the RSRG's previous experience of developing and undertaking lightweight software process assessments [32] the seven stage procedure for undertaking a Medi SPICE-Adept Assessment was defined. It was decided the assessment team should normally consist of two assessors who share responsibility for conducting the assessment. The seven stages of the procedure are as fol-lows: As a precursor to undertaking an assessment a preliminary meeting between the lead assessor and the company takes place. This is the first stage in the procedure and during this meeting the lead assessor discusses the main drivers for the company wishing to undertake an assessment. In this context the expectations regarding what can be realistically achieved are discussed and the procedure for undertaking the assessment is outlined. If there is agreement a schedule is drawn up. At the second stage the lead assessor has a meeting with the staff and management from the company who will be participating in the assessment where an overview of the Medi SPICE-Adept assessment method is presented and details of what their participation will involve is outlined. On the agreed date the onsite assessment commences which is the third stage in the procedure. For each process the lead assessor conducts interviews based on the scripted Medi SPICE-Adept questions with the relevant personnel and evaluates the responses. The second assessor who also participates in the interviews prepares interview notes and may ask additional questions when clarification is required. In addition work products may also be requested and briefly reviewed as part of this stage. A maximum of five processes are assessed in a single day with the interviews for each process taking approximately one hour. At the fourth stage the findings report is prepared off site based on the data gathered at stage three. Each process is reviewed in turn and where relevant particular strengths and issues (weaknesses) are identified based on the evaluation and interview notes. Suggested actions to address these issues and to facilitate process improvement are outlined and discussed. The possibility for the use of appropriate agile and lean practices is also considered. These are then documented and included in the findings report. This is a joint effort between the assessors and may include other SPI and/or lean and agile experts if required. The findings report is then presented to the management and staff who took part in the assessment which is the fifth stage in the procedure. Having provided adequate time for the findings report to be read and considered by the organization at the sixth stage the contents of

the report is discussed in detail with the relevant management and staff. At this point specific objectives for process improvement are collaboratively defined based on the findings report which results in the development of a process improvement plan. Given the lightweight nature of Medi SPICE-Adept improvements that offer the greatest benefits in terms of compliance, quality and the achievement of business goals are selected for inclusion in this plan. At the seventh stage in the procedure the organisation having implemented the process improvement plan have the opportunity of having the processes reassessed. Based on this, a final detailed report is prepared which highlights what has been achieved and an updated improvement plan is also provided.

4 Implementation of a Medi SPICE-Adept Assessment

Having developed the Medi SPICE-Adept Assessment method and the procedure for its implementation the first assessment took place in an Irish based medical device company Western Medical (a pseudonym). The company have been developing and selling medical devices for over thirty years. Each of their products contains both hardware and software and the role that software plays has considerably increase over the last number of years. They market their medical devices in the EU and the US so their products must conform to the MDD to receive the CE mark and the FDA regulations. Having agreed that an assessment would take place it was decided that the ten processes would be assessed over a two day period. This was undertaken by two assessors from the RSRG. Based on the results of the assessment a findings report was prepared and presented. The focus of the report was that for each process the company's strengths and issues were highlighted, in addition suggested actions to facilitate process improvement were also provided. Based on the findings report the process improvement objectives and process improvement plan were collaboratively defined and developed with the company. A summary of the issues identified for each process and the actions taken to address these issues and facilitate improvement were outlined in the process improvement plan as follows:

Requirements Elicitation - A serious problem which emerged from the assessment was that the requirements specification produced was too high level. It did not capture the level of detail required to facilitate product development and both the hardware and software engineers had to try to guess what some of the specific requirements were. Marketing took the place of the company's customers and would not commit on their exact requirements. To address this, the use of prototyping and user scenarios to define key product features to facilitate the development of a detailed and comprehensive requirements specification was agreed. Senior Management support was also sought to reinforce the importance of ensuring marketing's full participation in defining and signing off on requirements.

Systems Requirements Analysis - The need for a systems requirements specification document was identified and this was an important omission as it was also necessary for traceability. The high

level requirements specification was used in this process and it was not adequate as it lacked the necessary level of detail. In addition system requirements were not prioritised. It was agreed that a systems requirement specification would be developed based on the detailed requirements specification and that system requirements would be prioritised.

Configuration Management – While a configuration management tool was in place some key work products were not under configuration management and for those that were some important information was missing. In addition key features of the tool i.e. automatic merging was not being used. It was agreed that a configuration management strategy would be drawn up and implemented that ensured all the relevant work products were correctly managed and that the required level of detail was maintained. It was also agreed that all the relevant features of the tool would be updated and utilised.

Change Request Management - An ad-hoc change request management system was in place as a result requests were not prioritised, the level of detail provided was limited and the status of accepted change requests could not be determined until they were complete. To address these issues it was agreed that a formal change request management strategy would be developed and implemented. The selection of a tool to assist with this process would also be investigated. .

System Architectural Design - This process was dealt with in a very informal manner and a system architectural design specification was not produced. The IEC 62304:2006 requirement for a safety classification of each product was not addressed. This omission was important as this standard is now harmonized with the MDD and approved by the FDA. It was recommended and agreed that a formal system architectural design process would be put in place to facilitate the production of a system architectural design specification and to ensure that each product receives the relevant safety classification.

Software Construction - There was no defined strategy in place for performing unit testing. As a result it was carried out in an ad-hoc manner as the content and level of testing was left to the discretion of the individual tester. Documentation was not maintained and therefore test cases and results were not recorded. To address these issues it was agreed that a unit test strategy and procedures would be developed and implemented to ensure the required level of unit test coverage would be consistently provided and all unit test cases and results would be recorded.

Software Integration - There was no defined strategy for performing software integration or a documented integration plan. This process was therefore performed in an informal manner and the content and level of testing was left to the discretion of the individual tester. It was proposed and agreed that a software integration strategy should be developed and a software integration plan

defined. The integration test procedures should be evaluated for correctness and completeness and they should be consistently implemented. Integration test cases and test results should also be documented and recorded.

Software Testing - Specific software testing did not take place after software integration. The next tests undertaken were on the complete system which incorporated both hardware and software. The need for a software testing process was discussed and agreed in the light of the requirements of the medical device standards and in line with best practice. It was therefore proposed that a software testing strategy and procedures should be developed and implemented and test cases and results documented and recorded.

Verification - In general there were good verification procedures in place. One issue highlighted by the assessment was that code reviews were only performed very late in the process. To address this, it was agreed that code reviews would take place prior to unit testing.

The findings report was positively received by Western Medical as was the whole assessment procedure. The collaborative nature of the development of the process improvement plan provides motivation for its successful implementation. The plan is currently being implemented and when this is complete the opportunity to have the processes reassessed is available. While in this paper we have focused on the negative issues we identified the company had very good risk management and trace-ability procedures in place. It is important to state that Medi SPICE-Adept highlights the strengths as well as the weaknesses in an organization.

5 Conclusion

It is important to stress what the differences will be between a Medi SPICE assessment and Medi SPICE-Adept. Medi SPICE is a comprehensive and detailed domain specific process assessment and improvement model for medical device software development. When the model is complete a Medi SPICE assessment method will be developed which will facilitate in-depth analysis and assess-ment of each process and this will include the determination of its capability level. As a result the findings from a Medi SPICE assessment will be extensive, comprehensive and detailed. On the other hand Medi SPICE-Adept which is also based on the Medi SPICE model has a different purpose it is a lightweight assessment method. Its focus is more high level and its role is to provide a snap shot of key aspects of medical device software development processes and to assist with regulatory compli-ance and process improvement in this context.

Medi SPICE-Adept is the largest and most detailed lightweight assessment method developed by the RSRG. It is the result of industry demand and was developed to meet the requirement from a more extensive, but lightweight medical device software assessment method. A Medi SPICE-Adept assessment has recently been successfully implemented in Australia by our colleagues in Griffith University. Feedback from the Australian assessment was very positive and a specific request was that we include additional project management processes. This is in line with our strategy for Medi SPICE-Adept and we plan to incorporate the remaining thirty two Medi SPICE processes and twelve subprocesses in the coming year. Given the level of demand it is also our objective to carry out additional Medi SPICE-Adept assessments both in Ireland and in collaboration with our international colleagues.

6 Literature

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