The Development and Current Status of Medi SPICE

Valentine Casey, Fergal Mc Caffery

Regulated Software Research Group,
Dundalk Institute of Technology & Lero, Dundalk, Co Louth, Ireland
{Val.Casey, Fergal.McCaffery }@dkit.ie

Abstract. There is increasing demand for effective software process assessment and improvement in the medical device industry. This is due to the expanding and complex role that software now plays in the operation and functionality of medical devices. This paper outlines the development and current status of Medi SPICE a software process assessment and improvement model which is being developed to meet the specific requirements of this safety-critical domain. This includes the selection of the most appropriate software process improvement model on which to base Medi SPICE. Its initial development and restructuring to conform to ISO/IEC 15504-5:2012 and ISO/IEC 12207:2008. The structure and content of its process reference model is outlined and an industry based trial assessment of 11 of its processes discussed. Current and future work is considered including the timeframe for the release of a full version of the Medi SPICE model.

Keywords: Medical Device Software, Software Process Improvement, SPI, ISO/IEC 15504-5:2012, SPICE. ISO/IEC12207:2008, IEC 62304:2006.

1 Introduction

Medical device development is a highly regulated industry and the level of rigor required is determined by the potential hazard/risk the device may pose to patients, healthcare professionals and third parties [1]. Initially medical devices were composed of hardware, or had very limited software content. Over recent years this has changed and the role and importance that software plays has continued to increase [2]. In many situations this has necessitated the development and inclusion of increasingly large software components which facilitate the operation and increased functionality that medical devices now provide [3]. In these circumstances it is not surprising that the size, scope and complexity of medical device software has substantially increased [4].

The important role that software now plays in medical devices has been recognized by the European Union (EU). This is reflected in the latest amendment to the Medical Device Directive (MDD) (2007/47/EC) [5] which states standalone software may now be classified as an active medical device

in its own right. This is a significant development and in January 2012 the European Commission released a guidance document for the qualification and classification of standalone medical device software MEDDEV 2.1/ [6] to provide additional clarity on this important change.

The Food and Drug Administration (FDA) who are responsible for the regulation and approval of medical devices in the United Sates (US) have also recognized the increasingly important role that software plays in this domain. As a consequence they have published a number of software specific guidance documents for medical device software development over the last number of years. To remain up to date with current trends the FDA have recently published the *Medical Device Data Systems Final Rule* [7] and *Draft Guidance for Industry and Food and Drug Administration Staff - Mobile Medical Applications* [8].

Given the potential safety-critical nature of medical device software it must be developed in compliance with the relevant regulations and recommended international standards of the geographical location where the medical device is to be marketed to receive regulatory approval [9]. In order to market a medical device in the EU the receipt of the CE mark is essential and in the US FDA approval is required. In Australia, registration and approval is provided by the Therapeutic Goods Administration (TGA) and in Canada, by Health Canada. These and similar approval bodies in other countries recommend conformance to a number of international standards and technical reports to help achieve compliance with national regulatory requirements.   These include IEC 62304:2006 [10], ISO 14971:2007 [11], ISO 13485:2003 [12], EN 60601-4:2000 [13], IEC/TR 80002-1:2009 [14] , IEC 62366:2007 [15], IEC/TR 61508:2005 [16], and IEC 60812:2006 [17].

The level of regulatory compliance required is determined by the relevant regulatory body from a predefined classification scheme based on the potential risk/hazard posed by the medical device. This is typified by the FDA who have 3 levels of concern and the EU who have 4 classes based on perceived potential hazard, ranging from low risk to high risk. A Medical device is evaluated against the relevant scheme and a classification is determined. Based on this evaluation the organization developing the device is required to establish design controls in line with the medical device's classification level. The higher the classification of the device, the more stringent the design controls and constraints that must be complied with [18].

While regulatory bodies provide classification schemes, regulations, lists of approved or harmonized standards, technical reports and in some cases guidance documents the information is high-level and specific methods for performing the essential activities required have not been provided [19]. In these circumstances it is not surprising that medical device organizations producing software are compliance centric in their approach to its development. This has been compounded by the fact that a domain specific software process assessment and improvement model which addresses the specific requirements of the highly regulated medical device software industry has not been available. It is therefore not surprising that there has been very

limited adoption of software process improvement in the medical device industry [20].

This did not pose such a serious problem in the past when the level of software in medical devices was small and the role it played had a limited impact on the overall operation of the device. As stated this has now changed and there is a specific requirement for highly effective and efficient software development processes to be in place [21]. In addition these processes need to be defined and adopted to facilitate the production of the required deliverables in the correct manner in order to achieve regulatory approval [18].

To address this requirement the Regulated Software Research Group (RSRG) at Dundalk Institute of Technology (DkIT) is developing Medi SPICE [22] a medical device domain specific software process assessment and improvement model. The objective of Medi SPICE is to facilitate efficient medical device software process assessment and improvement by incorporating software engineering best practice coupled with the regulatory requirements of the medical device industry. This work is taking place in association with members of the SPICE User Group, members of relevant international standard bodies and representatives from the medical device software industry. This collaborative process is a key aspect of the development of Medi SPICE [23].

The remainder of this paper is structured as follows: Sections 2 outlines the initial development of what subsequently became Medi SPICE. Section 3 presents the development of Medi SPICE which includes the initial processes which were developed and the restructuring of the model which took place as a result of the release of ISO/IEC 12207:2008 [24] and ISO/IEC 15504-5:2012 [25]. The definition of the Medi SPICE Process Reference Model (PRM) and a trial assessment of 11 of its Process Assessment Model (PAM) processes are also discussed in this section. Section 4 concludes the paper with a brief overview of the current status of Medi SPICE and the schedule for the full release of the model.

2   The Initial Development of a Software Process Assessment and Improvement Model for the Medical Device Industry

Having identified the initial requirement for process improvement in the area of medical device software development a number of preliminary studies were undertaken [26]. This work culminated in an extensive literature review being carried out which focused on the development of a domain specific software process assessment and improvement model for the medical device industry [18]. This incorporated analysis of software process improvement models including the Capability Maturity Model[®] Integrated (CMMI[®]) [27] and ISO/IEC I5504-5:2006 [28]. While CMMI[®] and ISO/IEC I5504-5:2006 are effective and comprehensive models for general software development they

do not address the specific requirements which are essential for regulated software development [29]. For other safety critical industries this has resulted in the development and deployment of domain specific software process assessment and improvement models which includes Automotive SPICE [30] for the automotive industry and SPICE for SPACE [31].

It was recognized a similar approach was required for the medical device domain. To initiate this key aspects of medical device software development were focused on and gap analysis undertaken. This included the areas of Configuration Management and Software Risk Management. This resulted in the development of a Configuration Management Capability Model (CMCM) [32] and a Risk Management Capability Model (RMCM) [33] both for use in the medical device software Industry. These models were based on CMMI$^®$ and while they proved effective for the specific areas they addressed it was recognized that a more extensive approach was require. At this point a key question had to be considered which was should the CMMI$^®$ or ISO/IEC I5504-5:2006 be used at the basis for the development of a comprehensive medical device software process assessment and improvement model? The strengths of CMMI$^®$ and ISO 15504-5:2006 were both identified and evaluated in the context of the requirements of medical device software development. A key factor to emerge at this stage was the importance of IEC 62304:2006 *Medical device software—Software life cycle processes.*

2.1 IEC 62034:2006

As the medical device industry added software to their products consideration had to be given as to how that software could be developed. Having considered the alternatives ISO/IEC 12207:1995 [34] was selected as the most appropriate standard to implement for medical device software development. As with the use of other standards in this domain the goal was to minimized risk and the possibility of medical device failure. While ISO/IEC 12207:1995 was an effective standard it was developed for general software development and did not address the specific requirements of the medical device software industry [18]. This was highlighted by a review of the standard by the Association for the Advancement of Medical Instrumentation (AAMI) software committee. This resulted in the decision to develop and implement a new domain specific standard for medical device software development ANSI/AAMI SW68:2001 [35]. When this work was undertaken ISO/IEC 12207:1995 was used as the foundation on which ANSI/AAMI SW68:2001 was based.

ANSI/AAMI SW68:2001was revised and as a result a new standard IEC 62304:2006 was developed and released. The major differences between the two standards are that in IEC 62304:2006 three software safety classes are identified and a safety class is required to be assigned to each software system. Based on the assigned safety class specific processes and tasks are required. There is no longer a distinction made between primary and supporting processes and 2 processes were removed which had been part of

ANSI/AAMI SW68:2001. Some of the requirements from these processes were moved to other processes where relevant in IEC 62304:2006 [36].

IEC 62304:2006 provides coverage of the medical device software development processes. As a result this standard plays a key role in the development and maintenance of medical device software and is harmonized with the European MDD and is approved by the FDA as a consensus standard. IEC 62304:2006 is solely focused on software development and maintenance and does not address Requirements Elicitation and Validation which are considered system level processes. For the development of medical device software based on IEC 62304:2006 it is required that a Quality Management System (QMS) is in place e.g. ISO 13485:2003 [12] and a risk management process conformant with ISO/IEC 14971:2007 [11] is established.

As IEC 62304:2006 was developed based on ANSI/AAMI SW68:2001 as stated the relationship with ISO/IEC 12207:1995 has been maintained. This is highlighted in the standard as it states that its concepts and approach have been derived from ISO/IEC 12207:1995 AMD 1:2002 [37] and AMD 2:2004 [38] and have been tailored to the requirements for medical device software development. The differences in IEC 62304:2006 are outlined in Annex C.6 and they include:

a) The standard excludes system level processes.
b) Processes seen as duplicating activities which are documented elsewhere for medical devices are omitted.
c) A safety risk management process and software release process have been added
d) Documentation and verification are incorporated into the development and maintenance processes

The key relationship between the IEC 62304:2006 and ISO/IEC 12207:1995 AMD 1:2002 and AMD 2:2004 are also detailed at the process, task, and activity level in Table C.5 in Annex C.6.

2.2 The Selection of the Software Process Assessment and Improvement Model on Which to Base the Model for the Medical Device Industry

As a result of our preliminary studies and literature review the key relationship between IEC 62304:2006 and 12207:1995 AMD 1:2002 and AMD 2:2004 was defined and the level of its importance recognized as outlined in Section 2.1. While this was the case it was still important to evaluate CMMI® and its relationship to IEC 62304:2006. In 2009 the Software Engineering Institute published a white a paper "*CMMI and Medical Device Engineering*" [39] which presents a high-level description of how the CMMI® does not provide adequate coverage for medical device software developments with particular reference to IEC 62304:2006 [18]. The objective of the white paper was to help facilitate the extension of CMMI® to address this, but it also highlighted the considerable level of restructuring that would be required and the paper only considered this at a high level.

In contrast ISO/IEC 15504-5:2006 had been developed based on the PRM outlined in ISO/IEC 12207:1995 AMD 1:2002 and AMD 2:2004. As a result of our detailed analysis of both ISO/IEC 15504-5:2006 and IEC 62304:2006 it was clear there was direct relevance, and synergy between these standards. This was due to their common foundation, both being based on ISO/IEC 12207:1995 AMD 1:2002 and AMD 2:2004. In addition Automotive SPICE had been successfully developed and implemented [40] and it addressed a mission critical domain not dissimilar to Medical device software development. Having evaluated and analyzed the alternatives the decision was taken to base the development of the medical device software process assessment and improvement model on ISO/IEC 15504-5:2006. The title Medi SPICE was selected for the model to reflect this decision [22]. While it was recognized that where relevant ISO/IEC 15504-5:2006 would have to be amended and extended to meet the specific requirements of the medical device domain.

3 The Development of Medi SPICE

Having identified the specific requirements which needed to be addressed and having selected an overall structure and strategy the development of Medi SPICE commenced [19]. An initial task was the formal identification of the overall objectives of undertaking a Medi SPICE assessment. These were defined as to determine the state of a medical device organization's software processes and practices in relation to best practice and the regulatory requirements of the industry. The goal of such an assessment should be the identification of areas where process improvement can take place and to facilitate such improvement. It was also recognized that Medi SPICE should be capable of being utilized as part of a process to select software suppliers when an organization wishes to offshore or outsource part or all of their medical device software development. In this context Medi SPICE should be able to be used to evaluate the software process capability of third party or remote divisions and thereby provide key input into the selection process [41].

Work then commenced on the development of a preliminary Medi SPICE PRM. The initial focus was on the software engineering processes and some supporting processes. This preliminary PRM contained 11 processes:

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

- Software Validation

These processes were based on the structure of ISO/IEC 15504-5:2006, ISO/IEC 12207:1995 AMD 1:2002 and AMD 2:2004 and where relevant IEC 62034:2006. The outcomes defined incorporated best software engineering practice and the regulatory requirements of the medical device software domain. On completion, these processes were released for review by members of the SPICE User Group, international standards experts and representatives from the medical device software industry. Based on their feedback the processes were further updated and amended.

A key aspect of the development of Medi SPICE is the desire to ensure the model conforms to the latest revisions and additions to the medical device regulations, relevant international standards, technical reports and guidance documents. It soon became apparent with the release of ISO/IEC 12207:2008 that this would have a direct impact on the development of Medi SPICE.

3.1 The Release of ISO/IEC 12207:2008

The structure of ISO/IEC 12207:2008 is substantially different to that of ISO/IEC 12207:1995 AMD 1:2002 and AMD 2:2004. This is reflected in the name of ISO/IEC 12207:2008 Systems *and software engineering - Software life cycle processes* which highlights that the standard has been extensively revised. This took place in tandem with the revision of ISO/IEC 15288:2002 [42]. As a result it no longer just addresses the requirements of the software engineering life cycle processes it now also addresses the system engineering processes as well. This development has impacted on the revision of standards which have been derived from ISO/IEC 12207:1995 AMD 1:2002 and AMD 2:2004. In this context of particular relevance to Medi SPICE was the release of ISO/IEC 15504-5:2012 and the current revision of IEC 62034. ISO/IEC 15504-5:2012 now conforms to the structure of ISO/IEC 12207:2008. As part of the current revision of IEC 62034 to facilitate its next release a mapping was required to be undertaken between the processes of IEC 62034:2006 and ISO/IEC 12207:2008.

A member of the RSRG is also a member of the IEC SC62A JWG3 Standards Working Group (the IEC 62304 development team) and the RSRG were invited to contribute to this mapping. To facilitate this it was important to analyze in detail the relationship between IEC 62034:2006 and ISO/IEC 12207:1995 AMD 1:2002 and AMD 2:2004 which is documented in Table C.5 of the current version of the standard. A member of the RSRG prepared an extended version of this table to include the complete details of the ISO/IEC 12207:1995 AMD 1:2002 and AMD 2:2004 activities and tasks on which those of IEC 62304:2006 are based. As a result of analyzing this information and comparing it with ISO/IEC 12207:2008 a direct mapping was made.

Due to the restructuring that took place in ISO/IEC 12207:2008 the names and locations of a number of relevant processes, activities and tasks changed from the previous release of the standard. As a result of further analysis it

became clear that at the task level very minor adjustments had been made i.e. the term "developer" had been changed to "implementer" and notes have been added to some tasks. The only exception was the ISO/IEC 12207:1995 AMD 1:2002 and AMD 2:2004 task 6.4.2.2 Process Verification which had been removed from ISO/IEC 12207:2008. This is important as it is utilized in IEC 62304:2006 as the basis for the Verify Integration Tests Procedures task. Details of this analysis and mapping were documented and provided to the IEC SC62A JWG3 Standards Working Group to assist with the definition of the relationship between the next release of IEC 62304 and ISO/IEC 12207:2008.

3.1 The Development of the Structure of the Medi SPICE PRM

The selection of the appropriate processes for inclusion in the Medi SPICE PRM was a key activity. The objectives of this were twofold: one was the selection of effective life cycle processes which would facilitate medical device software development. The second was to facilitate conformance to the relevant medical device regulations, standards and guidance documents. To achieve this, a prepublication version of ISO/IEC 15504-5:2012, IEC 62304:2006 and ISO/IEC 12207:2008 were analyzed in detail. The analysis outlined in Section 3.1 on the mapping between IEC 62304:2006 and ISO/IEC 12207:2008 was of particular value in this context. This work was undertaken in tandem with an analysis of the relevant medical device regulations, standards, technical reports and guidance documents.   In this context particular reference was made to ISO 13485:2003 and ISO 14971:2007. Based on this analysis the structure of the Medi SPICE PRM was defined as consisting of a system life cycle processes category with 4 process groups and a software life cycle processes category with 3 process groups. Initially 42 processes and 15 subprocesses were identified. This included a medical device specific Software Risk Management process which was not part of ISO/IEC 15504-5:2012 or ISO/IEC 12207:2008. The addition of this process was necessitated by the requirements for medical device software development as outlined by IEC 62304:2006 and ISO 14971:2007.   The proposed structure of the Medi SPICE PRM was sent for review by members of the SPICE User Group, international standards experts and representatives of the medical device software industry. Based on their feedback the number of processes was increased to 44 with the addition of the Software Development Planning and Software Release processes.   As a result the Medi SPICE PRM was structured as follows:
System Life Cycle Processes Category
- 3 Agreement Processes and 7 Subprocesses;
- 6 Organizational Project - Enabling Processes and 6 Subprocesses;
- 7 Project Processes;
- 6 Organizational Project - Enabling Processes and 6 Subprocesses;
- 10 Technical Processes and 2 Subprocesses.
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Software Life Cycle Processes Category
- 8 Software Implementation Processes;
- 9 Software Support Processes (including Software Risk Management);
- 1 Supplementary Process.

3.2 The Development of the Initial Medi SPICE PRM & PAM Processes

Having defined the structure of the Medi SPICE PRM work began on the development of the PRM processes. It was decided to initially focus on the 13 processes which had a particular relevance to IEC 62034:2006. These processes are:
- Software Development Planning;
- Software Requirements Analysis;
- Software Architectural Design;
- Software Detailed Design;
- Software Construction;
- Software Integration;
- Software Qualification Testing;
- Software Release;
- Software Maintenance;
- Software Risk Management;
- Software Configuration Management;
- Software Change Request Management;
- Software Problem Resolution.

In line with ISO/IEC 15504-2:2003 [43] for each of these processes an ID, a process name and a process purpose was defined. Based on the process purpose outcomes were identified which incorporated best practice and the medical device software regulatory requirements. In this context the source of each outcome was recorded and where relevant each received an IEC 62304:2006 safety classification. The work carried out on the development of the preliminary PRM processes (outlined in Section 3) was of value when undertaking this task. On completion these PRM processes were sent for review by members of the SPICE User Group, international standards experts which included members of the IEC SC62A JWG3 Standards Working Group and representatives from the medical device software industry.

As a result of the positive feedback received from the reviewers it was decided to develop PAM processes for the 13 PRM processes in conformance with ISO/IEC 15504-2:2003. It was realized that this could facilitate an industry based trial assessment to take place of these processes. In this context the RSRG had been approached by a European based medical device company "Medical Incorporated" (a synonym) with the request that such a trial assessment of some of their software development processes should be undertaken. The 13 PAM processes were developed which involved the identification of the specific practices which facilitate the

achievement of the relevant process outcomes. The sources of the specific practices were annotated with reference to best practice and the medical device software regulatory requirements. Where relevant an IEC 62304:2006 safety classification was recorded for specific practices. For each process relevant input and output work products were also identified and recorded. These PAM processes were then reviewed by members of the SPICE User Group, international standards experts and representatives from the medical device software industry.

3.3 The Industry based Medi SPICE trial Assessment

Having received favorable feedback from the reviewers of the PAM processes, plans for undertaking the industry based Medi SPICE trial assessment commenced. The need for a qualified ISO/IEC 15504 assessor to undertake the assessment was recognized. Given the imbedded nature of the majority of medical device software and specifically of the software being assessed for Medical Incorporated the selection of an Automotive SPICE lead assessor was identified as appropriate. While this was the case it was also recognized that training would have to be provided to address the specific requirements of the medical device software domain. In consultation with the company 3 Automotive SPICE Assessors agreed to undertake the training and the assessment. They were a Lead Assessor, an Assessor and a Provisional Assessor. Having reviewed the PAM processes and based on the requirements of the company it was decided for the trial 12 of the 13 processes would be assessed and the Software Maintenance process was excluded.

A date for the assessment was agreed and the Assessors undertook the medical device domain specific training provided by the RSRG and reviewed the PAM processes in detail. It was also agreed that a member of the RSRG would participate in the assessment as a medical device software Technical Expert and provide support to the Assessors as and when required. The assessment took place over a 5 day period. Having commenced it was decided that 11 rather than 12 processes would be assessed as the project under review had not reached the Software Qualification Testing stage. The assessment was successfully undertaken and 8 processes were assessed as largely achieved at level 1 and 3 fully achieved. The results of the assessment were presented and discussed with the company. Based on the assessment results specific guidance was provided to Medical Incorporated to facilitate process improvement which was presented in the full findings report.

As this was a trial assessment it was important that the effectiveness of the Medi SPICE PAM processes were evaluated. To this end after the assessment the 3 Assessors were interviewed and they provided positive feedback on the content of the Medi SPICE PAM processes. With regard to the medical device domain training for the Assessors two issues were identified that required attention. These were the use of Software Of Unknown Provenance (SOUP) and the handling of residual risk. While these

had been discussed as part of the training it emerged during the assessment that the Assessors were confused about them with respect to medical device software development. These issues were clarified by the RSRG medical device software Technical Expert when they arose. These were discussed with the Assessors and it was important to ensure both of these topics were properly addressed as part of any future Assessor training program.

It was also important to evaluate the relevance and effectiveness of the Medi SPICE PRM processes and the assessment to the organization. To this end the Senior Technical Manager, Software Quality Manager, and a Senior Software Engineer who had all participated in the assessment were interviewed. Each highlighted the relevance of the focus placed on specific aspects of the processes being assessed. When required the assessment team's ability to explain what and why specific information was being requested was considered of value. Of particular importance was the final report which they considered presented a realistic assessment of their processes. The recommendations for improvement were recognized as relevant and of value and a process improvement program is planned based on the assessment findings. While it was clearly stated and recognized this was a trial assessment all aspects of the assessment and its outcomes were very positively received by Medical Incorporated.

4   Current Status and Future Plans

The development of the remaining Medi SPICE PRM processes is currently under way. The number of RSRG team members working on the development of Medi SPICE has recently been increased and it is now planned to release a draft version of the full Medi SPICE PRM by May 2013. It is also planned this will be followed by the release of the draft version of the full Medi SPICE PAM by September 2013. It is anticipated that a full release of the Medi SPICE model will take place in December 2013.

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