Medi SPICE and the Development of a Process Reference Model for Inclusion in IEC 62304

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Abstract: The demand for medical device software continues to grow and there is an associated increase in its importance and complexity. This paper discusses medical device software process assessment and improvement. It outlines Medi SPICE, a software process assessment and improvement model which is being developed to meet the specific safety-critical and regulatory requirements of the medical device domain. It also details the development of a subset of the Medi SPICE process reference model for inclusion in the next release of the IEC 62304 standard: *Medical device software - Software life cycle processes*. IEC 62304 is a key standard for medical device software development and is approved by many national regulatory bodies including the Food and Drug Administration in the United States and the European Union. This paper also outlines 3 lightweight software process assessment methods which have been developed in tandem with Medi SPICE. Finally the timeline for the release of the full Medi SPICE model is provided.

1 INTRODUCTION

Today Information Technology (IT) increasingly performs an essential role in the provision of healthcare services (Abraham et al., 2011). This is particularly reflected in the importance that IT now plays in medical diagnoses and treatment (Hanna et al., 2011). To facilitate this development the level of software functionality in medical devices and the complexity of that software has substantially increased (Rakitin, 2006). The importance that software now plays in medical devices has been acknowledged by the European Union (EU). This is demonstrated in the latest amendment to the Medical Device Directive (MDD) 2007/47/EC (European Council, 2007), which now recognizes that standalone software can be classified as an active medical device in its own right. Likewise in the United States (US) the Food and Drug Administration (FDA) have recently provided guidance in relation to medical device data systems (US FDA, 2011a) and draft guidance in relation to mobile applications for medical use (US FDA, 2011b).

While the importance that medical device software plays is now recognized, it is also realized that it can be difficult to both successfully develop and achieve regulatory approval for its placement on the market (Mc Caffery et al., 2010a). This is due to the safety-critical nature of medical device software which must be developed to comply with numerous specific regulations and international standards. These are dictated by the regulatory requirements of the geographical location where the medical device is to be marketed (Burton et al., 2006).

Although guidance is available from regulatory bodies in terms of what software activities must be performed, no specific methods for performing these activities are provided. As a result, medical device software development organizations have been compliance centric in their approach. This has therefore resulted in very limited adoption of software process improvement in the medical device domain (Denger et al., 2007). Until relatively recently, this was not such an important issue due to the limited proportion of software in medical devices. 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 from the relevant body (Mc Caffery et al., 2010a).

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To address the requirement to identify, assess, and assist with the implementation of these processes Medi SPICE is currently under development. The objective of Medi SPICE is to provide a software process assessment and improvement model that meets the specific requirements of the medical device industry (Mc Caffery and Dorling, 2010). The development of Medi SPICE is being undertaken by the Regulated Software Research Group (RSRG) at Dundalk Institute of Technology (DkIT) in association with the SPICE User Group, international standards bodies and representatives from the medical device software industry. This collaborative process is a key aspect of the development of Medi SPICE.

While a Medi SPICE assessment can be used to evaluate and initiate software process improvement, it may also be used for supplier selection. In this context, the results from an assessment may be used as criteria for selecting a supplier, when an organization wishes to outsource or offshore part or all of its medical device software development (Mc Caffery and Dorling, 2009). This is important, as today software has truly become a globally sourced commodity (Casey, 2010). As a result the level of globally distributed software medical device development continues to increase (Sudershana et al., 2007) (Klein et al., 2010). Given the mission critical nature of medical device software and the need for regulatory compliance, supplier selection is a key activity for medical device organizations and Medi SPICE can be utilized to help address this need.

The rest of this paper is structured as follows: In section 2, we discuss the regulatory requirements for medical device software development. In particular we focus on IEC 62304:2006 (IEC 62304:2006, 2006) and the important role it plays. We also consider the requirements for the next release of the IEC 62304 standard. In section 3, we provide an overview of Medi SPICE which includes its development, structure and processes. In section 4, we outline the development of the IEC 62304 Medi SPICE Process Reference Model (PRM). This is based on the structure of ISO/IEC 12207:2008 (ISO/IEC 12207:2008, 2008) and is a subset of the Medi SPICE PRM. It is planned that this PRM will be included in the appendix of the next release of the IEC 62304 standard. In section 5, we discuss the lightweight process assessment methods we have developed in tandem with Medi SPICE. We also briefly outline our findings from undertaking a lightweight Medi SPICE-Adept assessment in Ireland and Australia. Finally in sections 6, we provide our conclusions and future work including the timeline for the release of the full Medi SPICE process assessment and improvement model.

2 MEDICAL DEVICE SOFTWARE REGULATION

Regulations, international standards, technical reports and guidance documents play a key role in medical device software development. As stated this is due to the safety-critical nature of medical device software and the need for organizations developing such software to minimize the risk of failure and the prevention of harm to patients, clinicians and third parties. To address this, governments have defined regulatory requirements and established auditing bodies to ensure that only safe medical devices are placed on the market (Burton, 2009).

The FDA is responsible for medical device regulation and approval in the US. To provide assistance in achieving regulatory approval, the FDA have published a number of guidance documents which outline essential activities to be performed during software validation (US FDA Center for Devices and Radiological Health, 2002), pre-market submission (US FDA Center for Devices and Radiological Health, 2005) and when using off-the-shelf software in a medical device (US FDA Center for Devices and Radiological Health, 1999). Although the FDA guidance documents provide general information on which software activities should be performed, they do not provide specific details on how they should be undertaken.

In the EU the CE mark is required to market a medical device. The requirements for the achievement of the CE mark are outlined in the Medical Device Directive (MDD) 1993/42/EE (European Council, 1993) and its latest amendment MDD 2007/47/EC (European Council, 2007), the Active Implantable Medical Device Directive (AIMDD) 90/385/EEC (European Council, 1990) and the In-Vitro Diagnostic Directive (IVDD) 98/79/EC (European Council, 1998). The applicable directive(s) depend on the type of medical device being developed.

While these directives must be adhered to, they provide very limited information regarding the specific requirements for medical device software development. This is exemplified by the latest amendment MDD 2007/47/EC which states: "*For devices which incorporate software or which are medical software in themselves, the software must be*

validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification". The term "*state of the art*" is not defined and as a result many organizations developing medical device software for sale in the EU rely on the regulatory guidance documents provided by the FDA (Mc Caffery et al., 2010a).

In order to market a medical device in China, approval must be obtained from the State Food and Drug Administration (SFDA). In Australia, approval and registration is provided by the Therapeutic Goods Administration (TGA) and in Canada, by Health Canada. Auditing bodies performing similar roles exist in other countries including Brazil, Japan, India, South Korea, Singapore, Mexico and New Zealand.

To achieve compliance with national and regional regulatory requirements, conformance with a number of international standards and technical reports are recommended by auditing bodies, these include: IEC 62304:2006 (IEC 62304:2006, 2006), ISO 14971:2007 (ISO 14971:2007, 2007), ISO 13485:2003 (ISO 13485:2003, 2003), EN 60601-4:2000 (BS EN 60601-1-4:2000, 2000), IEC/TR 80002-1:2009 (IEC/TR 80002-1:2009, 2009) , IEC 62366:2007 (IEC 62366:2007, 2007), IEC/TR 61508:2005 (IEC/TR 61508:2005, 2005), and IEC 60812:2006 (IEC 60812:2006, 2006). A number of these standards are harmonized with the European MDD and approved by the FDA. These include ISO 14971:2007, ISO 13485:2003, and IEC 62304:2006.

2.1 Risk Management

To determine the level of regulatory compliance that is required for medical devices, auditing bodies have adopted predefined classification schemes based on hazard/risk posed by the medical device. The FDA has 3 levels of concern and in the EU the MDD has 4 classes based on perceived potential hazard, ranging from low risk to high risk. Medical devices are evaluated against the relevant scheme and classified. The manufacturer of the device is then 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 (Mc Caffery et al., 2010a).

ISO 14971:2007 *Medical Devices - Application of risk management to medical devices* is the de facto standard for medical device risk management (Burton, 2009). The FDA recognizes ISO 14971:2007 as an approved standard and considers compliance with it acceptable for meeting the risk management requirements for medical device premarket submissions. The FDA also provide their regulators with training in the standard as part of their software risk management training (Mc Caffery et al., 2010a). The EU also consider ISO 14971:2007 as a harmonized standard and conformance with the standard is acceptable for meeting the risk management requirements of the MDD (Harvey, 2003). In Canada, ISO 14971:2007 is a recognized standard by Health Canada. In both Japan and Australia, it has also become the industry standard for managing medical device risk.

While ISO 14971:2007 is the standard that medical device software organizations must conform to, it was developed to address the requirements of developing a medical device as a whole. Until relatively recently medical devices were mostly hardware with only a small level of software content. As a result there is a lack of specific information as to how ISO 14971:2007 should be applied for medical device software development. To address this a technical information report IEC/TR 80002-1:2009 was released to provide specific guidance on how ISO 14971:2007 should be applied when developing medical device software (Vogel, 2010).

2.2 Quality Management System

A key requirement for medical device development is that a quality management system is in place. The FDA define a quality system as "*the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management*" (US FDA, Revised April 1, 2011). By ensuring conformance to the requirements of a quality management system, medical device organizations have the structure and support in place to facilitate a controlled development environment. With the objective of providing greater reliability, safety, and the effectiveness of the devices they produce (Mc Caffery et al., 2010a). Conformance with the requirements of 21 CFR Part 820 *Quality System Regulations* (US FDA, Revised April 1, 2011) is central to achieving FDA approval in the US. ISO 13485:2003 *Medical device - Quality management systems- Requirements for regulatory purpose* is the international standard used for and audited against for medical device development. This standard is harmonized with the European MDD and recognized by the FDA.

2.3 Medical Device Software Life Cycle Processes

As software components were added to medical devices, manufacturers had to consider how software could be developed to ensure that it minimized risk and the possibility of failure. The medical device industry took the decision to recognize ISO/IEC 12207:1995 *Information Technology - Software life Cycle Processes* (ISO/IEC 12207:1995, 1995) (a general software engineering life cycle processes standard) to address this situation. Subsequently, the Association for the Advancement of Medical Instrumentation (AAMI) software committee reviewed ISO/IEC 12207:1995 and identified a number of shortcomings due to the fact that it was a generic standard.

As a result a decision was taken to create a new standard which was domain specific to medical device software development. When developing this standard the AAMI did not discard the work done with ISO/IEC 12207:1995 and used it as the foundation for AAMI SW68:2001 (ANSI/AAMI SW68:2001, 2001). In 2006, a new standard IEC 62304:2006 *Medical device software - Software life cycle processes*, was released which was based on the AAMI SW68:2001 standard.

IEC 62304:2006 is approved by the FDA and is harmonized with the European MDD. It provides coverage of the key medical device software development processes. Software developed using the IEC 62304:2006 standard is based on the assumption that it is developed and maintained in accordance with a quality management standard (e.g. ISO 13485:2003), and the risk management standard ISO/IEC 14971:2007. Both ISO 13485:2003 and ISO/IEC 14971:2007 are considered to be aligned standards with IEC 62304:2006 and their relationship is documented in (IEC 62304:2006, 2006).

IEC 62304:2006 is software specific in focus and does not address system level processes which include Requirements Elicitation and Validation. These are addressed by its aligned standards and ISO/IEC 15288: 2002 (ISO/IEC 15288:2002, 2002). ISO/IEC 12207:1995 AMD 1:2002 (ISO/IEC 12207:1995/Amd.1, 2002) and AMD 2:2004 (ISO/IEC 12207:1995/Amd.2, 2004). These are the foundations on which IEC 62304:2006 was developed and their relationship is documented in Annex C of the IEC 62304:2006 standard.

2.4 The Release of ISO/IEC 12207:2008

ISO/IEC 12207:1995 AMD 1 and AMD 2 was recognized as comprehensive in its approach to general software development and a number of standards in addition to IEC 62304:2006 were derived from it. These include ISO 15504-2:2003 (ISO/IEC 15504-2:2003, 2003), ISO/IEC 15504-5:2006 (ISO/IEC 15504-5:2006, 2006) and ISO/IEC 90003:2004 (ISO/IEC 90003:2004, 2004). The importance the standard plays is reflected in the fact ISO/IEC 15504-2:2003 and the ISO/IEC 15504-5:2006 PRM are derived directly from ISO/IEC 12207:1995 AMD 1 and AMD 2.

An extensive revision of the ISO/IEC 12207 standard took place. This was undertaken in parallel with the revision of ISO/IEC 15288:2002. This resulted in the release in 2008 of ISO/IEC 12207:2008 *Systems and software engineering - Software life cycle processes*. The focus of the new standard is no longer just the software engineering life cycle processes; it now addresses the system engineering processes as well. The structure of the standard has been amended to reflect this change.

As a result, standards which are derived from ISO/IEC 12207:1995 AMD 1 and AMD 2 are being updated to conform to the new structure of ISO/IEC 12207:2008. These include the next release of ISO/IEC 15504-5 and IEC 62304 which are currently under review. Medi SPICE will also conform to the new structure of ISO/IEC 12207:2008.

3 MEDI SPICE

As outlined in section 1, Medi SPICE is a software process assessment and improvement model which is being developed to meet the specific requirements of the medical device industry (Mc Caffery et al., 2010b). The results of a Medi SPICE assessment may be used to indicate the state of a medical device suppliers software practices in relation to the regulatory requirements of the industry, and identify areas for process improvement (Mc Caffery and Dorling, 2010). The results of an assessment may also be used as criteria for supplier selection (Mc Caffery and Dorling, 2009). The overall objective of Medi SPICE is to provide a conformity assessment scheme to support first, second or third party assessment results that may be recognized by the regulatory bodies.

Medi SPICE is based upon ISO/IEC 15504-5 and provides coverage of the medical device regulations,

and standards. These include the FDA regulations and guidelines, the European MDD and the associated approved and harmonized standards and technical reports (Mc Caffery et al., 2010a). Medi SPICE contains a PRM and a Process Assessment Model (PAM)

The development of Medi SPICE commenced in 2008 with an extensive literature review and a number of preliminary studies. This phase of the research culminated in the identification of the context and strategy for the development of Medi SPICE. This aspect of the research has been published in Medi SPICE: An Overview (Mc Caffery and Dorling, 2009), Medi SPICE Development (Mc Caffery and Dorling, 2010) and Software Process Improvement in the Medical Device Industry (Mc Caffery et al., 2010a). In 2010 work commenced on the development of a preliminary PRM and PAM (Mc Caffery et al., 2010b). The preliminary PRM & PAM 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 and ISO/IEC 12207:1995 AMD 1 and AMD 2. They were developed to meet the specific requirements of the relevant medical device regulations, standards and guidance documents. In addition, they also conformed to the requirements of ISO/IEC 15504-2:2003 for a PRM and PAM. On completion, these processes were released for review by the ISO/IEC 15504 community and representatives from the medical device software industry. These processes have been subsequently updated and amended to bring them in line with ISO/IEC 12207:2008 and the latest version of ISO/IEC 15504-5 (currently under ballot). In addition the number of processes has been increased.

3.1 The Medi Spice Process Reference Model (PRM)

The Medi SPICE PRM contains the set of medical device software lifecycle processes that are fundamental to the development of good quality medical device systems. The PRM outlines the purpose of each process and the outcomes that must be accomplished to achieve that purpose.

The Medi SPICE PRM contains 2 sets of life cycle processes. These are the Systems Life Cycle Processes and the Software Life Cycle Processes. These consist of 42 processes and 15 subprocesses which are structured as follows:

The System Life Cycle Processes (contains)

- 3 Agreement Processes and 7 Subprocesses;
- 6 Organizational Project - Enabling Processes and 6 Subprocesses;
- 7 Project Processes;
- 10 Technical Processes and 2 Subprocesses.

The Software Life Cycle Processes (contains)

- 6 Software Implementation Processes;
- 9 Software Support Processes which includes a medical device specific process Hazard Mitigation;
- 1 Supplementary Process

3.2 The Medi SPICE Process Assessment Model (PAM)

The Medi SPICE PAM is related to the Medi SPICE PRM and forms the basis for collecting evidence and the rating of process capability. To achieve this it provides 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 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. Indicators for process capability are generic practices that are applicable to any process and associated with process attributes, generic work products and generic resources that can be observed when a particular process attribute is achieved (ISO/IEC 15504-2:2003, 2003). In line with ISO/IEC 15504 the 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 prior to release.

3.3 The Medi SPICE and IEC 62304:2006

Given the importance of IEC 62304:2006 to medical device software development, conformance to this standard plays a key role in the development of Medi SPICE along with its aligned standards. As discussed in section 2, IEC 62304:2006 is currently being revised. As part of this revision, it is being aligned with ISO 12207:2008; it therefore requires that IEC 62304 should contain a PRM. As stated it is proposed the IEC 62304 revision will contain a subset of the Medi SPICE PRM (the Medi SPICE processes that will be included in the revision of IEC 62304). This will enable the relevant IEC 62304 processes to be comparable with those of ISO 12207:2008. It will also provide IEC 62304 with a PRM that may be used as the foundation for a process assessment model specifically for compliance with this standard.

4 DEVELOPMENT OF THE IEC 62304 MEDI SPICE PRM

The first step in the development of the IEC 62304 Medi SPICE PRM was the identification of the ISO/IEC 12207:2008 processes which were directly relevant to IEC 62304:2006. This was facilitated by the fact that IEC 62304:2006 documents its relationship to ISO/IEC 12207:1995 AMD 1 and AMD 2 at the process, activity and task level in Table C.5 of the standard.

Utilizing this information all the relevant IEC 62304:2006 processes, activities and tasks were identified and mapped against ISO/IEC 12207:2008. To achieve this a document was produced based on Table C.5 in the IEC 62304:2006 standard, but it was extended to include full details of the ISO/IEC 12207:1995 AMD 1 and AMD 2 tasks upon which the IEC 62304:2006 activities and tasks were based. In Table C.5 (within IEC 62304:2006) these tasks were only referenced. Analyzing this information and comparing it against ISO/IEC 12207:2008 allowed a direct mapping to be made between the processes and activities. The tasks were also analyzed in detail and any differences highlighted and evaluated.

Due to the restructuring that took place in ISO/IEC 12207:2008 and the changes required to facilitate this, the names and locations of a number of processes, activities and tasks changed from the previous release of the standard. While at the task level only cosmetic adjustments had been made i.e. the use of the term "*implementer*" instead of "*developer*" and the addition of brief notes to a limited number of tasks. The only relevant task omitted from ISO/IEC 12207:2008 which had been in ISO/IEC 12207:1995 AMD 1 and AMD 2 and referenced by IEC 62304:2006 was 6.4.2.2 Process Verification. This task had been used as the basis for the Verify Integration Tests Procedures task in IEC 62304:2006. While this task is absent from ISO/IEC 12207:2008 this is a requirement of IEC 62304:2006 and it was therefore retained in the Medi SPICE PRM.

Having identified the relevant ISO/IEC 12207:2008 processes these were compared with the Medi SPICE PRM processes and the next release of ISO/IEC 15504-5. This resulted in the selection of 13 processes for inclusion in the IEC 62304 Medi SPICE PRM. This included an extra process Hazard Mitigation which is not an ISO/IEC 12207:2008 process as it is medical device software specific.

The processes which were identified as suitable for inclusion in the IEC 62304 PRM are as follows:

- Software Implementation
- Software Operation
- Software Maintenance
- Software Requirements Analysis
- Software Architectural Design
- Software Detailed Design
- Software Construction
- Software Integration
- Software Qualification Testing
- Software Configuration Management
- Software Problem Resolution
- Hazard Mitigation
- Software Change Request Management

The relationship between these processes and IEC 62304:2006 are detailed in figure 1.

The set of processes were then reviewed by both members of the IEC SC62A JWG3 Standards Working Group (the IEC 62304 development team) and the ISO/IEC 15504 community. Having agreed the processes, development of the IEC 62304 Medi SPICE PRM commenced. Each process was developed in line with the requirements of a PRM as defined in ISO/IEC 15504-2:2003 (ISO/IEC 15504-2:2003, 2003). This included assigning a process ID, a process name and defining a process purpose.

MEDI SPICE PROCESSES	IEC 62304:2006 PROCESSES & ACTIVITIES
TECHNICAL PROCESSES	
ENG.4 Software Implementation	5.Software Development Process 5.1 Software Development Planning
ENG.9 Software Operation	5.8 Software Release
ENG.10 Software Maintenance	6. Software Maintenace
SOFTWARE IMPLEMENTATION PROCESSES	
DEV.1 Software Requirements Analysis	5.2 Software Requirements Analysis
DEV.2 Software Architectural Design	5.3 Software Architectural Design
DEV.3 Software Detailed Design	5.4 Software Detailed Design
DEV.4 Software Construction	5.5 Software Unit Implemenation and Verification
DEV.5 Software Integration	5.6 Software Integration and Integration Testing
DEV.6 Software Qualification Testing	5.7 Software System Testing
SOFTWARE SUPPORT PROCESSES	
SUP.2 Software Configuration Management	8. Software Configuration Management*
SUP.8 Software problem resolution	9. Software Problem Resolution
SUP.9 Hazard Mitigation	7.Software Risk Management
SUPPLEMENTARY PROCESSES	
SP.1 Software Change Request Management	8. Software Configuration Management*

*Denotes where a ISO 62304:2006 process is addressed in more than 1 Medi SPICE Process

Figure 1: The IEC 62304 Medi SPICE PRM processes for inclusion in the IEC 62304 PRM and their relationship to IEC 62304:2006.

Based on the process purpose outcomes were identified. The objective of each outcome was to contribute to the achievement of the process purpose. While the purpose and outcomes addressed the requirements of medical device software development and IEC 62304:2006 they were also inclusive of the requirements of the aligned, medical device standards and regulations. These included the FDA regulations and guidance documents, the requirements of the European MDD, ISO 14971:2007, ISO 13485:2003 and IEC/TR 80002-1:2009. The PRM recorded the source of each outcome and where relevant each outcome received an IEC 62304 safety classification. Once the IEC 62304 Medi SPICE PRM was complete it was sent for review and evaluation by the ISO/IEC 15504 community and the IEC SC62A JWG3 Standards Working Group. Based on the successful completion of these reviews and receipt of approval from the Standards Working Group it is now planned to include the IEC 62304 Medi SPICE PRM in the Appendix of the forthcoming release of IEC 62304.

5 THE DEVELOPMENT OF LIGHTWEIGHT ASSESSMENT METHODS

An important part of this ongoing research has been the development of 3 lightweight medical device software process centric assessment methods. The first was Med-Adept (Mc Caffery and Casey, 2010) which is a lightweight assessment method that provides a means of assessing the software engineering capability of processes in relation to medical device software development. The goal of a Med-Adept assessment is to provide organizations who may be considering developing medical device software with an understanding of what they would need to have in place before embarking on such a strategy. To date a total of 8 Med-Adept assessments have taken place.

Traceability plays a key role in the development of regulatory compliant medical device software (Mc Caffery and Casey, 2011). Med–Trace was developed as an assessment method specifically to assist companies to adhere to the traceability aspects of the medical device software standards (Casey and Mc Caffery, 2011). The objective of Med-Trace is to enable software development organizations to gain an appreciation of fundamental traceability best practices, based on the software engineering traceability literature, software engineering process models, and the medical device software guidelines and standards. To achieve this, Med-Trace may be used to diagnose an organization's weaknesses and strengths with relation to their medical device software development traceability practices. Med-Trace assessments have taken place in 4 companies and another 1 is currently in the planning stage.

The third lightweight assessment method is Medi SPICE-Adept (Mc Caffery et al., 2011). This method was initially based on the assessment of the 11 processes which made up the preliminary Medi SPICE PRM and PAM. While these were the initial processes selected for Medi SPICE-Adept. These have been updated and will be expanded to provide coverage of all the Medi SPICE processes and

subprocesses.

Medi SPICE-Adept provides organizations with a lightweight assessment of each of the processes they select with the Medi SPICE Model. This covers conformance to the specific requirements of the medical device regulations, standards, and guidance documents. It also provides a method for carrying out an assessment, against the requirements for best software engineering practice for each process. That said, it is a lightweight method and the objective of undertaking a Medi SPICE-Adept assessment, is not to receive formal certification or a capability rating. Rather it is to identify an organization's strengths and weaknesses and to initiate and facilitate process improvement.

5.1 Implementation of Medi SPICE-Adept

The first Medi SPICE-Adept assessment took place in an Irish based medical device company Western Medical (a pseudonym). The company selected 10 processes and these were assessed over a two day period. Based on the results of the assessment, a findings report was prepared and presented. Process improvement objectives and a process improvement plan were collaboratively defined and developed with the company, based on the findings report. The improvement plan is currently being implemented and when this is complete the processes will be reassessed. A final detailed report will then be prepared and an updated improvement plan will also be provided.

The findings report and improvement plan were very positively received by Western Medical as was the whole assessment procedure. A Medi SPICE-Adept assessment has also recently been successfully implemented in Australia by colleagues in Griffith University. The Australian assessment provided similar positive feedback. Given the level of demand the RSRG will continue to carry out additional Medi SPICE-Adept assessments both in Ireland and in collaboration with international colleagues.

5.2 The Rationale for Developing Lightweight Assessment Methods

There was a specific demand in the industry for the development of each of these lightweight assessment methods and their introduction has been welcomed. While this was the case, the purpose of their development was not solely to address these requirements. The implementation of each of these methods has allowed key aspects of Medi SPICE to be tested and refined in an industrial setting. It has also provided relevant feedback which has been documented and incorporated into subsequent iterations of the Medi SPICE model. This is seen as a key element in the development of Medi SPICE. This was also the rationale for the development of the lightweight assessment methods in tandem with the development of Medi SPICE.

6 CONCLUSIONS

It was decided in 2011 that Medi SPICE would conform to the structure of ISO/IEC 12207:2008 and the latest version of ISO/IEC 15504-5 (currently under ballot). As outlined in section 3 the structure and processes which make up the current version of the Medi SPICE PRM were selected and agreed. Work on the detailed development of the PRM commenced.

Following the invitation to add a subset of the Medi SPICE PRM to the next release of the IEC 62304 standard, work commenced on the production of the IEC 62304 Medi SPICE PRM. As outlined in Section 4 this work is now complete. The development of the remaining Medi SPICE PRM and PAM processes is currently under way. The full Medi SPICE PRM is scheduled for release in September 2012. This will be followed by the release of the Medi SPICE PAM by the end of December 2012. This will see the release of the full Medi SPICE process assessment and improvement model by January 2013. At that stage additonal research will be undertaken on its implementation and to facilitate continued improvement.

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