Implementation of a Hybrid Low Overhead Assessment Method for Medical Device Software Development

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Abstract

The need for software is increasingly growing in the medical device industry. Even though the primary concern of medical device software development is safety, medical device software development organisations are also concerned with time and budget overruns, plus ensuring that the customer requirements are fulfilled. At present the medical device software industry lacks strategies to combine adhering to mandatory regulatory guidelines with increasing the quality of the software developed. Software process improvement (SPI) assists software development organizations to increase their software quality, and assessments are an integral part of this process. Unfortunately, software process assessments are often expensive and time consuming. Additionally, they often provide companies with a long list of issues without providing realistic suggestions. The goal of this paper is to describe the implementation of a new low-overhead hybrid assessment method that has been designed specifically for medical device software development organisations wishing to improve their software development practices. This assessment method combines the SPI models of the Capability Maturity Model Integration (CMMI) and ISO/IEC 15504-5 with medical device software development regulations.

1. Introduction

Due to the safety-critical nature of the medical devices, organizations developing medical device software are expected to produce high-quality software through the use of defined processes.

Medical device companies must comply with the regulatory requirements of the countries in which they wish to sell their devices. Compliance requirements stipulate that the manufacturers must produce a design history file detailing the software components and processes undertaken in the development of their medical devices. Due to the safety-critical nature of medical device software it is important that highly effective software development practices are in place within medical device companies. Although guidance exists from regulatory bodies on what software activities must be performed, no specific method for performing these activities is outlined or enforced.

To tackle these issues, governments have put in place regulatory bodies whose job it is to define regulatory systems for medical devices and to ensure that only safe medical devices are placed on the market. A safe device is one which cannot cause serious injury to a patient or end-user of the device.

Medical device companies must comply with the medical device regulations stipulated by regulatory bodies governing the country in which they to wish to market their device. The medical device companies must be able to produce sufficient evidence to support their claims of compliance. To this end, in the USA, the Center for Devices and Radiological Health (CDRH) has published guidance papers which include risk-based activities to be performed during software validation [1], pre-market submission [2] and when using off-the-shelf software in a medical device [3]. Although the CDRH guidance documents provide information on which software activities should be performed, they do not enforce any specific method for performing these activities. Much of the guidance provided is ambiguous and does not provide details on how software activities should be performed. This information is spread across various regulatory guidance papers, industry guidance papers, standards and technical implementation reports. The obvious implication

of this is that medical device manufacturers could fail to comply with the expected requirements.

Within the medical device industry a decision was made to recognise the ISO/IEC 12207 [4] software engineering standard for general medical device software development. However, the Association for the Advancement of Medical Instrumentation (AAMI) software committee carefully reviewed the ISO/IEC 12207 standard and decided it was necessary to create a new standard specifically for medical device software development. This was due to a number of gaps in the existing standard in relation to medical device software regulations. For example, the existing ISO/IEC 12207 standard required major changes for those companies who already had existing software processes in place and did not account for off-the-shelf (OTS) software requirements.

However, the AAMI did not discard the work done with the ISO/IEC 12207 standard and instead used it as the foundation for their new standard "AAMI SW68, Medical device software – Software lifecycle processes". AAMI SW68 [5] defines two major lifecycle processes i.e. - a development process and a maintenance process. The SW68 standard was produced with both application software and embedded software in mind. Where a medical device comprises software or is used in conjunction with software, the standard considers the software to be a sub-system of the medical device itself. In 2006, a new standard AAMI/IEC 62304 [6] was released that was based on the AAMI SW68 standard.

Whenever we mention medical device guidelines within this paper we refer to the following medical device standards and guidelines: ANSI/AAMI/IEC 62304, FDA [1,2,3,7], European Council Guidelines [8], ISO 14971 [9], EN 60601-1-4 [10], TIR 32 [11], GAMP 5 [12], AAMI/IEC 61508 [13] and IEC 60812 [14].

2. SPI Models

SPI initiatives can be based on various models such as the Capability Maturity Model Integration (CMMI) [15] or process standards such as ISO 15504-5 [16] and ISO 9001 [17, 18]. Implementation of changes identified during SPI assessments enable organizations to reduce software development costs [17,18, 19]. For example, 400 projects reported increased productivity as a result of implementing CMMI based improvement programmes [19]. This study reported a 12% reduction in software product development times and a 49% reduction in defects through using CMM/CMMI based improvement programmes. However, many companies are reluctant to adopt the assessment part of these models as they feel that they are too cumbersome and expensive for small organisations [20].

The first step in engaging in SPI is to assess the current state of an organization's software development practices. A SPI path may be developed based upon a combination of this starting point and the business goals of the organisation [21]. Processes in small organisations must be catered for in a different manner than within large companies [22] as existing SPI assessment methods are very cumbersome and are not suited to the needs of small organisations. Consequently, small companies need specialized assessment methods as they do not have the same resources to invest in SPI as large organisations. However, they require high quality software and efficient software development [23].

Organizational maturity indicators like CMMI levels, ISO/IEC 15504 ratings or specific ISO standards have become important for software development. Customer organisations often rely on them when selecting a supplier as the results of these assessments can serve as an indicator of process maturity.

This paper presents how a lightweight software process assessment method (Med-Adept) has been developed for the medical device software industry. This method has been specifically developed to provide a low cost way of providing:

- Non-medical device software development organisations with an assessment of how their existing software development practices will be required to change in order to become medical device software suppliers.
- Existing medical device software development organisations with an assessment of how effective their existing software development practices are in relation to developing high quality software and adhering to medical device regulations

The Med-Adept method integrates processes from CMMI and ISO/IEC 15504-5 with practices specified in medical device regulatory guidelines and standards.

3. The Need for Med-Adept

One of the main goals of the Regulated Software Research Group in Dundalk Institute of Technology is to support the growth of a medical device software development industry within Ireland. The Adept method [21] was previously developed to provide a light-weight assessment of software processes from CMMI and ISO/IEC 15504-5. The Adept method has now been integrated with practices specified in medical device regulatory guidelines and standards to produce Med-Adept. Med-Adept is an assessment method that provides a means of assessing the software engineering capability for processes in relation to medical device software (both application and embedded software).

Med-Adept enables software development organisations to gain an appreciation of the fundamental processes from CMMI, ISO/IEC 15504-5 and AAMI/IEC 62304 (including additional practices required by other medical device guidelines and standards) through diagnosing strengths and weaknesses in their software development practices. Med-Adept was designed to adhere to 8 of the 10 criteria outlined by Anacleto et al. [24], for the development of lightweight assessment methods: low cost, detailed description of the assessment process, guidance for process selection, detailed definition of the assessment model, support for identification of risks and improvement suggestions, conformity with ISO/IEC 15504, no specific software engineering knowledge required from companies' representatives, and tool support is provided. The two exceptions to the criteria outlined Anacleto et al. [24], are that no support is provided for high-level process modeling and only the authors currently have access to method. Med-Adept also inherits the following requirements from Adept: improvement is more important than certification, a rating is not required, preparation time required by the company is minimised; assessment time is minimized, and companies should be enabled to select assessment in process areas that are most relevant to their business goals.

While the main aims of Med-Adept are to either encourage non-medical device software development organisations to develop software for the medical device industry or to improve the software development processes within existing medical device software development organizations. Additionally, the Med-Adept method provides an ideal opportunity to educate software development organisations in terms of generic SPI. Therefore, the assessment would not be pointless if a non-medical device software development company did not become a medical device software development company in the future. Consequently, Med-Adept provides medical device specific and non-medical device specific recommendations. Assessed companies are also supplied with feedback in relation to both CMMI and ISO/IEC 15504-5 which enables such companies to decide whether they wish to follow a CMMI or an ISO/IEC 15504-5 improvement path. Med-Adept provides the assessed company with a findings document presented in terms of processes from CMMI, ISO/IEC 15504-5 and practices required by medical device software standards and regulations (with a particular focus on AAMI/IEC 62304).

4. Development of the Med-Adept Method

As Med-Adept is based upon the Adept method, existing Adept questions were used as the foundation for the Med-Adept method. Questions were added to enable coverage of medical device regulations. Even though each assessment component adopts a CMMI process area name, it also contains questions providing coverage of relevant ISO/IEC 15504-5 processes and medical device standards and regulations (see table 1).

Table 1 – Structure of Med-Adept

Med- Adept Processes		
Adept Processes		
Selected CMMI Process Area	**Selected ISO/IEC 15504-5 Process**	**AAMI/IEC 62304 Process**
Risk Management	Risk Management	Risk Management
Configuration Management	Configuration Management	Configuration Management
Requirements Management Requirements Development	Requirements Elicitation Software Requirements Analysis	Software Requirements Analysis
Project Planning Project Monitoring & Control	Project Management	Software Development Planning
Technical Solution	Software Design Software Construction	Software Architectural Design Software Detailed Design
Product Integration	Software Integration	Software Integration
Validation, Verification	Software Testing Verification Validation	Software Unit Implementation and Verification Integration Testing Software System Testing
Process and Product Quality Assurance	Quality Management System	ISO 13485 B.10 Quality Assurance
Measurement and Analysis		
		Software Release Software Maintenance Software Problem Resolution Documentation Software Safety Classification

Table 1, illustrates that medical device regulatory questions are added for 11 of the 12 Adept processes, the exception being Measurement and Analysis which cannot be mapped against the processes of AAMI/IEC 62304. Additionally, the existing Adept processes (which Med-Adept is founded upon) do not provide coverage of 5 AAMI/IEC 62304 processes (Software Release, Software Maintenance, Software Problem Solution, Documentation, Software Safety Classification). Therefore, the pilot version of Med-Adept also does not provide coverage of these processes. Additionally, it should also be noted that pilot release of Med-Adept does not include the +SAFE [25] process areas that have been added as a safety extension to the CMMI model, or the safety extensions that will be released in 15504-10, or the Software Safety Classification process from AAMI/IEC 62304.

Therefore in its current state Med-Adept will not provide complete coverage of all the medical device regulations and will need to be extended in the future to provide complete coverage. However, the main aim of Med-Adept is not to provide comprehensive coverage of medical device regulations, but rather to assist organisations to improve their software practices and to encourage organizations to develop medical device software. To encourage uptake of the Med-Adept assessment by software SMEs, on-site interviewing is restricted to one day [21] thus minimising the time and cost associated with the assessment.

4.1. Scripted Med-Adept Questions

Table 2 illustrates the breakdown of the scripted Med-Adept questions. When developing the interview questions we examined the base practices, checking the relevant interview questions from the Adept method to ensure coverage of their counterparts in the medical device regulations. There is some commonality between related processes in CMMI, ISO/IEC 15504-5 and AAMI/IEC 62304. However Med-Adept questions based solely upon a process within one model will not (in isolation) provide full coverage of this process within the other two models (this is illustrated in figure 1 for the risk management and configuration management processes).

Table 2. Breakdown of Scripted Med-Adept Questions

AHAA Interviews	No. of Adept Questions	No. of New Questions	No. of Med-Adept Questions
Risk Management	39	23	62
Configuration Management	39	2	41

4.2. Risk Management

Within Adept 39 questions were used to provide coverage of the specific goals of the CMMI and the base practices of ISO/IEC 1504-5 for Risk Management. Med-Adept is more comprehensive in its coverage of Risk Management and has 62 scripted questions for Risk Management (see Table 2). Med-Adept not only contains CMMI and ISO/IEC 15504-5 based questions but also 23 additional questions that are specifically related to the Risk Management process of AAMI/IEC 62304 and other associated medical device standards and regulations. Figure 1, illustrates that out of the 33 scripted questions that are applicable to the CMMI model, 8 are applicable to both ISO/IEC 15504-5 and medical device regulations, 9 are applicable to ISO/IEC 15504-5, 17 are applicable from an medical device regulatory perspective, and 15 are only applicable to the CMMI model. Out of the 46 scripted questions that are applicable to the medical device regulations, 8 are applicable to both ISO/IEC 15504-5 and CMMI, 6 are applicable to ISO/IEC 15504-5, 9 are applicable from a CMMI perspective, and 23 are only applicable to the medical device regulations. Out of the 15 scripted questions that are applicable to the ISO/IEC 15504-5, 8 are applicable to both medical device regulations and CMMI, 14 are applicable to medical device regulations, 1 is applicable from a CMMI perspective, and none are only applicable to ISO/IEC 15504-5.

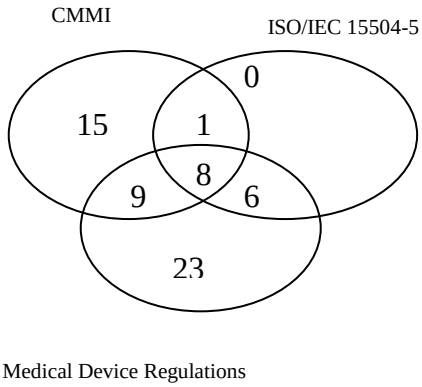

Figure 1. Breakdown of Risk Management Questions

For example, establishing a risk management strategy is an important part of risk management. The Med-Adept method has 17 scripted questions that are asked to gain an understanding of the company's procedure for establishing a risk management strategy for a project (see Table 3).

These questions provide coverage of this topic in CMMI, ISO/IEC 15504 and the medical device regulations. Ten questions are asked which are only applicable in relation to medical device regulations. Two questions are asked that are based solely on the CMMI model and these are used to determine where the risk management strategy is documented and the tools that are used to support the risk management process. Two questions are applicable to CMMI, ISO/IEC 15504-5 and medical device regulations practices and these questions probe the existence of a risk management strategy and if this strategy covers different stages of a lifecycle model. Three questions are applicable to both ISO/IEC 15504-5 and the medical device regulations. These questions are used to determine the scope of risk management within the organisations and whether it is at an organisational or a group level and to gain an understanding in relation to how risk is monitored. Configuration management questions were analysed in the same manner, providing a list of 41 scripted questions.

4.3 Med-Adept Stages

Med-Adept is composed of eight stages. The assessment team (normally) consists of two assessors who conduct the assessment between them.

Stage 1 involves a preliminary meeting between the assessment team and the software company wishing to undergo a software process assessment. The assessment team discuss the main drivers for the company embarking upon a Med-Adept assessment and establish whether the company is interested in developing software for the medical device industry. During stage 2 the lead assessor provides an overview of Med-Adept for members of the assessed organisation who will be involved in subsequent stages. This session is used to remove any concerns that individuals may have.

Table 3. Med-Adept Questions for Establishing a risk management strategy

Question	CMMI	ISO/IEC 15504-5	Medical Device Regulations
Do you determine the scope of the risk management to be performed		Yes	Yes
Do you have a risk management strategy? - What kind of things does this include?	Yes	Yes	Yes
Do you include lifecycles phases for which the strategy is applicable ?	Yes	Yes	Yes
Do you use any tools to support risk management?	Yes		
Where is the risk management strategy documented?	Yes		
Do you define appropriate strategies and risk measures to identify, analyse, treat and monitor each risk or set of risks		Yes	Yes
Is this both at the project and organisational level.		Yes	Yes
Do you set acceptability levels for each risk or set of risks, both at the project and organizational level			Yes
Do you include a verification plan as part of the strategy			Yes
Do you outline the allocation of responsibilities			Yes
Do you outline the requirements for reviewing the RM activities			Yes
Do you analyse post-production queries and bugs			Yes
Do you include at least one person in the RM activity that was involved in the software development, with both relevant medical device and RM knowledge along with the date of the analysis			Yes
Is this person(s) identified on the report along with the date of the analysis			Yes
Do you determine software hazards			Yes
Does your RM strategy include Off-The-Shelf Software as a potential hazard?			Yes
Do you include hardware failures as a potential hazard			Yes

Stage 3 provides a brief insight into project documentation. However, the primary source of data for Med-Adept is through a series of process interviews conducted during stage 4. In this stage key staff members from the assessed organisation are interviewed. There is an interview for each process. Each interview is scheduled to last approximately 1.5 hours. To enable stage 4 to be completed within 1 day we restrict the scope of a single Med-Adept assessment to 4 processes. Each interview (normally) involves two assessors and at least one representative from the company. Stage 5 is a collaborative exercise between the assessors to develop the findings report using interview notes for each of the assessed processes. The resultant findings report consists of a list of strengths, issues and suggested actions for each of the assessed processes.

Stage 6 involves presenting the findings report to participating staff in the organisation. Stage 7 involves collaborating with staff to develop a roadmap. This will provide guidance to the assessed company presenting practices that will provide the greatest benefit in terms of the company's business goals. Companies wishing to develop software for the medical device industry are recommended to focus upon establishing working practices that will assist them to fulfil the medical device regulations. Stage 8 involves revisiting the assessed company approximately 3 to 6 months after the completion of stage 7 and reviewing progress against the SPI path. The outcome of this stage is an updated SPI path and a final report detailing the progress that has been accomplished along with additional recommendations. This stage provides feedback and assistance to the assessed company after a period of time and also assists in compiling research material in terms of SPI experiences.

5. Med-Adept Implementation

We implemented a Med-Adept assessment in the Irish site of a multinational medical device organization, MedSoft (a pseudonym). MedSoft did not develop electronic based medical devices but rather used software to control the manufacture of its medical devices. MedSoft wanted to understand their current software development practices and the extent to which these practices would have to change to comply with recent medical device standards such AAMI/IEC 62304. However, their primary interest was to determine if SPI practices could be introduced that would assist them to improve the efficiency and quality of their current risk management and configuration management practices. As this was a pilot assessment it was restricted to the processes of risk management and configuration management. MedSoft also sought a resource-light method to obtain guidance as to how they could improve these 2 processes. MedSoft was therefore an ideal candidate for a Med-Adept assessment.

During stage 1 of the Med-Adept assessment the goals and schedule of the assessment were determined, involving an assessor (normally 2 assessors would participate in a Med-Adept assessment however as this was a pilot assessment involving only 2 processes and 2 interviewees we decided that one assessor would be sufficient), a software development manager and a software engineer from MedSoft. It was discovered during stage 1 that the software development manager and the software engineer chosen to participate in the assessment both play pivotal roles in MedSoft's risk management and configuration management processes. During stage 2 the assessor provided an overview briefing of Med-Adept to the software development manager and the software engineer. The assessor briefly inspected a sample risk management plan, sample minutes from project review meetings and a configuration management document (Stage 3). This enabled the assessor to gain a basic understanding of the documentation procedures within MedSoft, and also assisted the assessor to develop additional (MedSoft specific) questions for the process interviews.

During stage 5 the assessor developed a findings report, listing strengths and issues for each of the 2 assessed processes. This report also provided recommendations as to how to address the issues that were highlighted. The recommendations were also based on the business goals that were highlighted in stage 2. The main business goal that emerged was that more efficient risk management and configuration management regulatory complaint processes were desired. The findings report was then presented to the software development manager and the software engineer that participated in the Med-Adept assessment (stage 6).

5.1 Risk Management Findings

The Risk Management process interview contained 62 scripted questions. Performance of the Med-Adept assessment method generated 11strengths, 24 issues and 21 recommendations for the risk management process (see Table 4). The action part of the table illustrates how suggestions (RMAct1-21) were provided to address each of the issues (RMIss1-24) that arose during the Med-Adept assessment.

Table 4. Med-Adept Risk Management Findings

Strength	Description of Strengths
RMStr1	Patient risk is documented
RMStr2	RM is documented as part of the company's procedure
RMStr3	RM is considered at the project level
RMStr4	Ownership is assigned to Risks
RMStr5	Acceptability levels are set for project risks
RMStr6	The RM activity involves participants who are knowledgeable in software development and RM
RMStr7	Risk documentation templates exist for Process, Patient and Technical Risk
RMStr8	Risks are evaluated, categorised and prioritised on new systems
RMStr9	Possible impact of risk is considered on new systems
RMStr10	All RM activities are recorded for new systems
RMStr11	Hardware failure is included as a potential hazard
Issue No.	**Description of Issues**
RMIss1	No risk list of known risks held that can be used a starting point for analysing risks on new projects
RMIss2	Assessment of risk likelihood depends on the experience of the team
RMIss3	No thresholds are set to trigger management activities
RMIss4	Thresholds are not set on risks for executing mitigation or contingency plans
RMIss5	Acceptable risk levels not set for all risks
RMIss6	No documented set of steps for reducing the likelihood and consequences of risk to an acceptable level
RMIss7	No individual RM strategy –it forms part of the overall procedures
RMIss8	Project risk is not defined
RMIss9	Risk is not defined by project
RMIss10	Risk is not conducted at an organisational level
RMIss11	Nothing documented in relation to assisting the determination of hazards E.g. Off-the-shelf software is not defined as a potential hazard
RMIss12	All elements of the WBS or project plan are not reviewed for risks on all projects
RMIss13	No procedure for looking for new risk at any occurrence of technical or managerial decisions
RMIss14	RM procedures are less efficient on old systems
RMIss15	Recorded RM activities may be lost over time on old systems
RMIss16	Low priority risks may be ignored
RMIss17	RM is performed only at the initial stages of the project
RMIss18	Do not continuously assess changes in the status of a risk
RMIss19	No formal template exists for project risk
RMIss20	Mitigation and Contingency Plans are not in place for all risks
RMIss21	Mitigation and Contingency Plans that are in place are not verified
RMIss22	Do not assess the effectiveness of risk treatment actions
RMIss23	No timeline for risk handling activities
RMIss24	Only highest priority risks are focused upon for mitigation and contingency

Action No:	Description of Actions
RMAct1	Develop an Organisational RM Strategy
RMAct2	Develop a Project RM Plan consisting of patient risk, technical risk, process risk. Consider hazards as part of this. E.g. Off-the-Shelf Software, Hardware Failure, Environment
RMAct3	Initiate the development of a risk list
RMAct4	Risk list repository should be built containing sources of risk and hazards that may be referenced upon the commencement of a new project
RMAct5	Risk list repository should contain previously encountered risks, common risks etc.
RMAct6	Risk list repository should be split into categories as some risks may be more appropriate for particular types of projects
RMAct7	Risk list repository should contain sample acceptability levels for each risk
RMAct8	Risk list repository should contain sample steps for reducing the likelihood and consequence of particular risks
RMAct9	Risk list repository should contain sample thresholds for executing mitigation or contingency plans
RMAct10	Initiate the development of a formal template for identifying risks
RMAct11	Include Context, Conditions and Consequences of the risk in the risk template
RMAct12	Include both patient and project risk types in the template:
RMAct13	When performing Risk Identification • Examine each part of the WBS or project plan for risks • Use the risk list to help identify risks • Document the risk using the Risk Identification Template
RMAct14	Analyse and Prioritise ALL Risks Evaluate the probability and the consequence of the occurrence of the risk
RMAct15	Set threshold values for activating risk handling activities Use the records of similar risks in the risk list repository to assist with these steps
RMAct16	Develop Risk Mitigation and Contingency Plans for ALL risks not just high priority ones
RMAct17	Verify these Risk Mitigation and Contingency plans
RMAct18	Perform RM activities throughout all stages of the project and not just at the initial stages
RMAct19	Continuously monitor the status of risks
RMAct20	Apply risk handling actions (if a risk exceeds an acceptability threshold) until the level of the risk is deemed acceptable
RMAct21	Assess the effectiveness of risk handling actions and update the risk list repository with this information and improvements etc.

Figure 2, provides a summary of MedSoft risk management practices within 7 practice areas. Each practice area consists of practices required by the CMMI, ISO/IEC 15504-5 and medical device regulations. Within figure 2, 0.0 indicates that a practice area is not performed whereas, 1.0 indicates that all sub-practices within a practice area are fully performed. The 7 practice areas are as follows:

- Determine Risk Sources and Categories
- Define Risk Parameters
- Establish a Risk Management Strategy
- Identify Risks
- Evaluate, Categorise, and Prioritise Risks
- Develop Risk Mitigation Plans
- Implement Risk Mitigation Plans

For example, table 3 demonstrates how establishing a risk management strategy area consists of 17 questions that provide coverage of this practice area within CMMI, ISO/IEC 15504-5 and the medical device regulations. Figure 2, illustrates that MedSoft appears quite strong in the practice areas of "Determining risk sources and categories", "Establishing a risk management strategy" and "Evaluating, Categorising and prioritizing risks". However, even these practice areas still require improvement and issues also arose within these areas. For example, even though a risk management strategy was established there was no procedure in place for identifying new risks at any occurrence of technical or managerial decisions within this strategy. The practice areas of "Defining risk parameters", "Developing Mitigation Plans" and in particular "Implementing risk mitigation plans" were quite weak with a number of issues identified for these areas (see figure 2). Implementation of the suggested actions will improve each of the 7 practice areas, but in particular will greatly strengthen weaker practice areas such as "Implement risk mitigation plans".

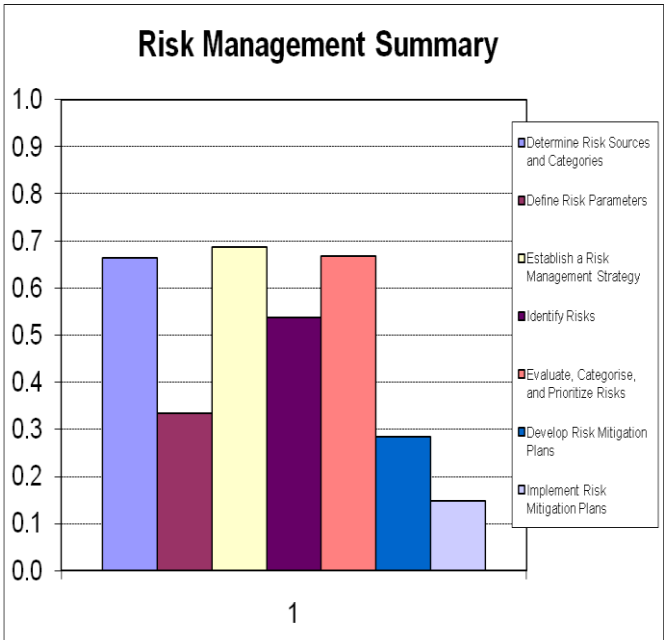

Figure 2. Summary of the Med-Adept capability of the assessed risk management practices within MedSoft

5.2 Summary of the Configuration Management Findings

Upon assessment of the Configuration Management process within MedSoft using Med-Adept (largely based upon the 41 scripted questions) we discovered that Configuration Management was generally a well applied process in MedSoft (see figure 3). Most work products

were tightly controlled, with both code and documentation being placed under configuration control using a tool that was developed internally within the organization. Well defined procedures were in place for the control, management, prioritisation and peer-review of change requests with evidence to suggest that the quality assurance team are quite successful at managing configuration issues. Additionally, an up-to-date description is kept of configuration items, with a log of change items being retrievable from the internal configuration management tool. Also, whenever a new baseline have been created this is published to the entire team.

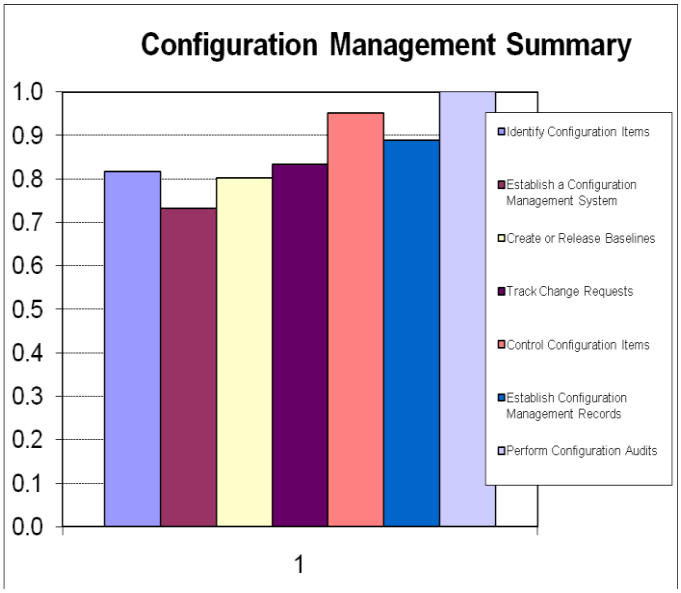

Figure 3. Summary of the Med-Adept capability of the assessed configuration management practices within MedSoft

However, despite the fact that configuration management is performed well within MedSoft a number of issues were also highlighted and recommendations were provided to address these issues. Here are some examples:

- Too much detail was defined in terms of change requests, particularly in the case of very small changes as the same level of detail was required for small changes as very large changes;
- On average it took between 4 to 6 months for any change to be approved – even in the case of very small changes;
- The configuration management system had a flat structure as opposed to a hierarchical one;
- The internal configuration management tool was used more for control than for management and other tools had to be used e.g. Gemini, SourceSafe, Sharepoint for management activities;
- Some items that are not under configuration control were used in baselines.

6. Summary and Conclusions

Prior to this assessment MedSoft were not familiar with either AAMI/IEC 62304 or its predecessor SW68 and whilst they had heard of CMMI and ISO/IEC 15504-5 they had never engaged in implementing either of them. Upon analysis, the Med-Adept assessment revealed that MedSoft may be able to significantly improve their risk management development practices by adopting the recommendations suggested in the findings report through implementing the suggested practices. Additionally, even though MedSoft's current configuration management processes are very strong in terms of control they could be improved in terms of management and the adoption of the suggestions recommended in the Med-Adept findings report would enable MedSoft to have both strong configuration and management practices.

The MedSoft software development manager felt that the assessment was beneficial to the organisation in a number of respects. First, it provided MedSoft with knowledge and some high-level training in relation to CMMI and ISO/IEC 15504-5 practices for Risk Management and Configuration Management. Second, it provided MedSoft with an insight into the practices that are required by the medical device regulations in order to achieve compliance for these areas, and in particular it provided an introduction to the importance of the AAMI/IEC 62304 standard for the development of medical device software. Third, MedSoft liked the fact that the assessment required no preparation on their behalf and that very little time was required to perform the assessment. Fourth, MedSoft found it very useful to have an external audit of their configuration management and risk management processes so that issues could be highlighted and plans put in place to resolve these issues. Fifth, MedSoft recognised the importance of receiving external guidance in relation to improving their configuration management and risk management processes.

During the findings presentation, the software development manager and the engineer both agreed that the highlighted strengths and issues were an accurate reflection of company's risk management and configuration management practices. Both the management and developers of MedSoft acknowledged that the Med-Adept recommendations were achievable and if implemented could bring benefit.

The software development manager from MedSoft also stated that they intended championing these improvements

in the site the assessment was performed within and then rolling them out to other locations so that the overall organisation could benefit from incorporating the recommendations into their configuration management and risk management practices.

Following the Med-Adept findings presentation, MedSoft representatives met internally to discuss developing a SPI path. They reviewed and prioritised all the Med-Adept recommendations, planning how they will be implemented in a new project (stage 7 of Med-Adept).

Having gone through this assessment cycle, management realised the importance of such assessments. Therefore, a criticism of the Med-Adept which they made was that they were only assessed in 2 processes. We have agreed to engage in an additional assessment involving other software processes (i.e. 2nd release of Med-Adept). They also have requested that we re-assess their software processes within 6 months (perform stage 8 of the Med-Adept) so that they may obtain feedback in relation to their progress along their SPI path. This will also provide the assessment team with an opportunity to validate their improvement suggestions.

This paper presents how a Med-Adept assessment was conducted in a medical device software company. The company has since prioritised actions and are currently engaged in adopting a number of the recommendations as part of their software development practices. It also describes a pilot release of the Med-Adept method, providing coverage of 2 processes. In the future we plan to extend the number of processes that may be assessed. We will extend the Med-Adept assessment to provide coverage of the remaining nine applicable processes that are displayed in table 1.

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