**Medi SPICE: An Overview**

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**Abstract**

 This paper outlines the development of a software process assessment and improvement model (Medi SPICE) specifically for the medical device industry. The paper details how medical device regulations may be satisfied by extending relevant practices from ISO/IEC 15504-5.

Medi SPICE will consist of a Process Reference Model and a Process Assessment Model. The Medi SPICE Process Assessment Model will be used to perform conformant assessments of the software process capability of medical device suppliers in accordance with the requirements of ISO/IEC 15504-2: 2003. The Medi SPICE Process Assessment Model is based on ISO/IEC 15504-5: 2006 but will also provide coverage of additional software development practices that are required to achieve regulatory compliance within the medical device industry.

**1. Introduction**

Medical device companies 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.

Medical device companies who market within the USA must ensure that they comply with medical device regulations as governed by the FDA (FDA - Food and Drug Administration) [1,2,3,4]. The medical device companies must be able to produce sufficient evidence to support compliance in this area. To this end, the Center for Devices and Radiological Health (CDRH) has published guidance papers for industry and medical device staff which include risk based activities to be performed during software validation [2], pre-market submission [3] and when using off-the-shelf software in a medical device [4]. Although the CDRH guidance documents provide information on which software activities should be performed, including risk based activities; they do not enforce any specific method for performing these activities.

This paper highlights the need for a software process improvement (SPI) model within the medical device industry (Medi SPICE) and draws upon the call for specific software development standards to be developed for the medical device industry so that companies adhering to such standards will have a more streamlined pathway towards FDA compliance. Medi SPICE has the aim of minimising the volume of software documentation content within the premarket submission to the FDA for audit and to provide global harmonization (with consistent guidance provided for all medical device software manufacture) [5]. 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. The results of these assessments may also be used as a criterion for supplier selection. The authors believe that, with the publication of the Medi SPICE Process Reference and Process Assessment Models, more specific guidance will be available for the basis of process design and assessment in the medical device industry.

We describe the early stage development of Medi SPICE based upon applicable processes from the ISO/IEC 15504-5 [6] model. The ISO/IEC 15504-5 model is being used as a foundation upon which to develop this model. We also illustrate high-level mappings that have been performed between medical device regulations and ISO/IEC 15504-5 processes.

Medi SPICE will consist of amended ISO/IEC 15504-5 processes. However we initially concentrate upon the ISO/IEC 15504-5 processes that are deemed most applicable to the regulatory requirements of the medical device industry.

**2. The development of Medi SPICE**

To perform this research project, the team plan to deliver a Process Reference Model (PRM) and Process Assessment Model (PAM) which will contain processes that will provide comprehensive coverage of all the FDA and European Council guidelines [7], and associated standards (e.g. ISO 14971[8], IEC 60601-1-4 [9], IEC 62304 [10], TIR 32 [11], GAMP [12, 13]) for the complete software development lifecycle. As safety is a primary issue for medical device software, the PRM and PAM will incorporate:

* the safety integrity levels and the safety life cycle from the international standard for the “functional safety” of electrical, electronic, and programmable electronic equipment (IEC 61508) [14];
* the safety processes that are present in +SAFE [15]. These will be introduced in part 10 of ISO/IEC 15504. The scope of Part 10 is to develop a Safety Extension that defines additional processes and guidance to support the use of the exemplar process assessment models for systems and software (ISO/IEC 15504 Parts 5 and 6) when applied to the assessment of safety related systems in order to make consistent judgement regarding process capability and/or improvement priorities.

An overall objective will be to propose a conformity assessment scheme to support first, second or third party assessment results that may be recognised by the regulatory bodies. The PRM and PAM of the Medi SPICE assessment standard will be derived from all 48 ISO/IEC 15504-5 processes as they are all applicable to the development of safety-critical medical device software. As the IEC 62304 standard contains the medical device software lifecycle processes that have to be adhered to in order to achieve medical device regulatory compliance a key objective will be to provide coverage of all processes that are either included in or referenced from IEC 62304.

**3. Project outline**

The Medi SPICE PRM and PAM will consist of a defined set of software processes that will contain base practices which when utilised will assist medical device software development organisations to fulfil the regulatory guidelines and standards of the medical device industry. Medi SPICE will cover the complete medical device software development and maintenance lifecycle. The Medi SPICE PAM will provide guidance in relation to assessing the software engineering capability of processes within a medical device software development organization, which will be conformant with the ISO/IEC 15504-2 [16] requirements for a PAM. Medi SPICE will be based upon integrating defined IEC 62304 processes into relevant ISO/IEC 15504-5 processes to enable FDA guidelines to be fulfilled. Additionally, we will also incorporate the safety processes from +SAFE and various other medical device related standards into relevant processes e.g. ISO 14971 into the risk management process. The FDA have defined the following eleven software development areas:

* *Level of Concern*
* *Software Description*
* *Device Hazard and Risk Analysis*
* *Software Requirements Specification*
* *Architecture Design*
* *Design Specifications*
* *Requirements Traceability Analysis*
* *Development*
* *Validation, Verification and Testing*
* *Revision Level History*
* *Unresolved Anomalies*

The IEC 62304 Medical device software – Software lifecycle processes standard defines a number of process requirements that should be adhered to, these are as follows:

*Quality Management System,*

*Software Safety Classification,*

*Software Development Process,* which includes:

* Software Development Planning
* Software Requirements Analysis
* Software Architectural Design
* Software Detailed Design
* Software Unit Implementation & Verification
* Software Integration & Integration Testing
* Software System Testing
* Software Release

*Software Maintenance Process*, which includes:

* Establish Software Maintenance Plan
* Problem & Modification Analysis
* Modification Implementation

*Risk Management Process,* which includes:

* Analysis of software contributing to hazardous situations
* Risk Control measures
* Verification of risk control measures
* Risk management of software changes

*Software Configuration Management Process*, including:

* Configuration Identification
* Change Control
* Configuration status accounting

*Software Problem Resolution Process*, which includes:

* Prepare problem reports
* Investigate the Problem
* Advise Relevant Parties
* Use change control process
* Maintain Records
* Analyse problems for trends
* Verify software problem resolution
* Test documentation contents

Medi SPICE is being developed to instill effective practices into the software development processes of medical device companies. This is an attempt to improve the effectiveness and efficiency of software practices used by medical device companies through investigating the mapping between relevant ISO/IEC 15504-5 processes, the eleven FDA software development areas and the 5 process area groups defined in IEC 62304. At present ISO/IEC 15504-5 consists of 48 processes, however, it should be noted that 3 new safety based processes will be added in Part 10 of ISO/IEC 15504.

All 48 ISO/IEC 15504-5 processes are applicable to the development of safety-critical medical device software and may be included in Medi SPICE. However, in order to progress Medi SPICE a small number of pilot processes will initially be developed. This set of processes will then be expanded until Medi SPICE contains a complete set of processes that will fulfil all the associated regulatory standards and guidelines. Our approach will be to agree upon a base set of processes that will satisfy the eleven software development areas defined by the FDA, +SAFE processes, the European Council, and the main process groups (i.e. Software Development, Software Maintenance. Software Risk Management, Software Configuration Management, Software Problem Resolution) that are defined in IEC 62304.

The Medi SPICE PRM will contain a process name, a purpose, and outcomes for each of the processes. In addition to this information the PAM will also contain the following information for each process: the set of base practices required to accomplish the process purpose and fulfill the process outcomes; sample output work products; characteristics associated with each work product.

Table 1, illustrates the result of performing a high-level mapping of requested FDA pre-market submission areas and IEC 62304 processes against existing ISO/IEC 15504-5 processes. From performing this mapping it was evident that there would not be an exact one-to-one mapping from an FDA area to both an IEC 62304 process and a ISO/IEC 15504-5 process and that overlaps exist. Table 1 has grouped together processes were the most significant overlaps occur, however it should be noted that other less significant overlaps will also occur across groups. The table includes the 11 software areas that are defined by the FDA, these are mapped against 14 processes that are defined in IEC 62304 plus the 2 + SAFE processes, which are in turn mapped against 23 ISO/IEC 15504-5 processes and 3 additional safety related processes that will be included in ISO/IEC 15504 Part 10 - i.e. Safety Management, Safety Engineering & Selection and qualification of software tools and libraries. It should be noted that whilst other ISO/IEC 15504-5 processes are relevant for developing medical device software, we feel that the 23 ISO/IEC 15504-5 processes listed are the most relevant (from the set of 48 processes). These processes will be extended with medical device specific content to include safety integrity levels and to satisfy the associated medical device requirements included in both the FDA guidelines and ISO/IEC 62304.

We initially considered developing Medi SPICE to solely focus upon the medical device regulations and to use the IEC 62304 processes as the foundation. However, our aim is for medical device companies not only to develop software that will adhere to the regulatory guidelines but also to encourage the adoption of medical device software development processes that will lead to the development of safer and more reliable medical device software. We feel that this will be achieved through following established software engineering practices such as those documented in ISO/IEC 15504-5.

**Table 1. Mapping FDA software areas and IEC 62304 processes against ISO/IEC 15504-5**

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| --- | --- | --- |
| **FDA Areas** | **Associated IEC 62304 Processes** | **Associated ISO/IEC 15504-5 Processes** |
| ***Risk and Safety Management Group*** |
| 1. Device Hazard and Risk Analysis
2. Level of Concern
* ***+SAFE – A Safety extension to CMMI***

 CMMI Process Areas* Safety Management
* Safety Engineering
 | 1. Risk Management
2. Software Safety Classification
 | **A1. Risk Management** **A2. Safety Management** (Part 10 Safety Extensions)**A3. Safety Engineering** (Part 10 Safety Extensions) |
| ***Requirements Group*** |
| 3. Software Requirements Specification 4. Requirements Traceability Analysis | 1. Software Requirements Analysis
 | *B.1 Requirements Elicitation***A.4 Software Requirements Analysis** *B.2 System Requirements Analysis*  |
| ***Development Group*** |
| 5. Architecture Design Chart6. Design Specifications7. Software Description8. Software Development Environment Description | 1. Software Development Planning
2. Software Architectural Design
3. Software Detailed Design
 | **A.5 Project Management****A.6. Selection and qualification of software tools and libraries** (Part 10 Safety Extensions)*B.3 System Architectural Design***A.7 Software Design***B.4 Documentation* |
| ***Testing and Integration Group*** |
| 9. Validation, Verification and Testing | 1. Software Unit Implementation and Verification
2. Software Integration and Integration Testing
3. Software System Testing
 | **A.8 Software Construction****A.9 Software Integration** **A.10 Software Testing***B.5 System Integration**B.6 System Testing***A.11 Verification****A.12 Validation** |
| ***Supporting Processes*** |
| 10. Revision Level History11. Unresolved Anomalies | 10. Software Release11. Software Configuration Management12. Software Maintenance 13. Software Problem Resolution  | *B.7 Product Release**B.8 Product Acceptance Support**B.9 Software Installation***A.13 Configuration Management****A.14 Problem Resolution Management****A.15 Change Request Management****A.16 Software and System Maintenance** |
| ***Additional Requirements*** |
|  | 14. Quality Management System | ISO 13485*B.10 Quality Assurance* |

From closer inspection of table 1, it may be recognised that 16 of the associated ISO/IEC 15504-5 processes appear in **bold** and are labelled with an **A** and the remaining 10 processes (in *italics*) are labelled with a *B*. The **A** processes are ISO/IEC 15504-5 processes of which a high proportion of their defined base practices will be required either in their current state or in a revised state to satisfy the regulatory demands of the medical device industry. The *B* processes are ISO/IEC 15504-5 processes which contain a much smaller proportion of defined base practices that will be required either in their current state or in a revised state to satisfy the regulatory demands of the medical device industry. **The 16 A processes are:**

*Risk Management*

*Safety Management* (to be included in Part 10)

*Safety Engineering* (to be included in Part 10)

*Selection and qualification of software tools and libraries* (to be included in Part 10)

*Software Requirements Analysis*

*Project Management*

*Software Design*

*Software Construction*

*Software Integration*

*Software Testing*

*Verification*

*Validation*

*Configuration Management*

*Problem Resolution Management*

*Change Request Management*

*Software and System Maintenance*

**The 10 *B* processes are:**

*Requirements Elicitation*

*System Requirements Analysis*

*System Architectural Design*

*Documentation*

*System Integration*

*Product Release*

*Product Acceptance Support*

*System Testing*

*System Installation*

*Quality Assurance*

**3.1. Medi SPICE Delivery Phases**

We will initially focus on the development of the above 16 **A** Medi SPICE processes. Table 2, illustrates that Medi SPICE will be delivered in 3 phases. Phase 1 will consist of delivery of the 16 most relevant processes. Phase 2, will consist of the delivery of 26 processes and phase 3 will consist of the delivery of all 51 Medi SPICE processes. The mappings between the regulatory guidelines and the relevant ISO/IEC 15504-5 processes will then produce Medi SPICE processes that retain the ISO/IEC 15504-5 process names.

**Table 2. Different Phases of Medi SPICE delivery**

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| --- | --- | --- |
| **Medi SPICE Phases** | **ISO/IEC 15504-5 Processes to be extended** | **Resultant Medi SPICE Processes** |
| **Phase 1** | A1. Risk ManagementA2. Safety Management (Part 10)A3. Safety Engineering (Part 10)A4. Software Requirements AnalysisA5. Project ManagementA6. Selection and qualification of software tools and libraries (Part 10)A.7 Software DesignA.8 Software ConstructionA.9 Software IntegrationA.10 Software TestingA.11 VerificationA.12 ValidationA.13 Configuration ManagementA.14 Problem Resolution ManagementA.15 Change Request ManagementA.16 Software and System Maintenance | Risk ManagementSafety Management Safety EngineeringSoftware Requirements AnalysisProject ManagementSelection and qualification of software tools and libraries Software DesignSoftware ConstructionSoftware IntegrationSoftware TestingVerificationValidationConfiguration ManagementProblem Resolution ManagementChange Request ManagementSoftware and System Maintenance |
| **Phase 2** | B1. Requirements ElicitationB2. System Requirements AnalysisB3. System Architectural DesignB4. DocumentationB5. System IntegrationB6. Product ReleaseB7. Product Acceptance SupportB8. System TestingB9. System InstallationB10. Quality Assurance | **16 Phase 1 processes****+**Requirements ElicitationSystem Requirements AnalysisSystem Architectural DesignDocumentationSystem IntegrationProduct ReleaseProduct Acceptance SupportSystem TestingSystem InstallationQuality Assurance |
| **Phase 3** | 25 Remaining ISO/IEC 15504-5 Processes | **26 (Phase 1& Phase 2) processes****+**25 Remaining Processes |

Like ISO/IEC 15504-5, each of the Medi SPICE processes will consist of a purpose, a number of outcomes and a number of base practices that will have to be performed in order to fulfil the outcomes. The performance of the base practices provides an indication of the extent of achievement of the process purpose and process outcomes. Work products are either used, produced or both, when performing the process [6]. The composition of the Medi SPICE processes is illustrated in figure 1.

X

Y

Z

**X**- ISO/IEC 15504-5 Practices that are not mandatory for regulatory compliance.

**Y**- ISO/IEC 15504-5 Practices that are required for regulatory compliance.

**Z**- Non-ISO/IEC 15504-5 Practices that are required for regulatory compliance.

Figure 1. Composition of Medi SPICE processes.

Medi SPICE will highlight what additional base practices and outcomes have to be added to the associated ISO/IEC 15504-5 processes in order to satisfy medical device regulations (Z), as well as any ISO/IEC 15504-5 outcomes and associated base practices that are not required in order to satisfy medical device regulatory requirements (X). Due to the scale of the entire Medi SPICE model the remainder of this paper will present a summary of the risk management process as this is a very important process in relation to the development of safety-critical software for the medical device industry.

**4. Medi SPICE risk management process**

The Medi SPICE Risk Management (RM) process seeks to combine the various guidelines and standards within the medical device industry. It does so in the context of the following regulations: ISO 14971, SW68, IEC 62304, TIR32 and GAMP 4/GAMP 5 and FDA guidance documents. The RM process outlined in this paper was developed following an extensive literature review of standards and CDRH guidance papers which govern the medical device software industry. This paper describes an integral part of this research by detailing the development of a Medi SPICE RM process that is based upon the ISO/IEC 15504-5 RM process. Upon development, the Medi SPICE RM process will be an extension of the ISO/IEC 15504-5 RM process that is specifically tailored to fulfil the RM regulations of the medical device software industry. The RM process may then be adopted by medical device companies to improve their software development practices by providing them with a process that will ensure that their hazard analysis and risk control procedures satisfy the current medical device regulations and guidelines. The Failure Mode and Effects Analysis (FMEA) method of identifying, mitigating and tracking risk and hazard issues will be used within the RM process [17].

This section briefly summarises a mapping of the medical device standards and guidelines against the ISO/IEC 15504-5 RM process. The Medi SPICE RM process is developed through mapping regulatory medical device practices against the seven base practices specified in ISO/IEC 15504-5 for RM. These are as follows:

* BP1: Establish risk management scope;
* BP2: Define risk management strategies;
* BP3: Identify risks;
* BP4: Analyse risks;
* BP5: Define and perform risk treatment actions;
* BP6: Monitor risks;
* BP7: Take preventative or corrective action.

Within Medi SPICE each base practice consists of 1 or more base sub-practices. The following is an example of the “BP1: Establish risk management scope” base practice within Medi SPICE. The aim of this practice is to determine the scope of the RM to be performed. Both ISO/IEC 15504-5 and the medical device regulations specify that the RM scope should be defined. Additionally, the medical standards specify that the strategy should include the life-cycle phases for which the strategy is applicable (see table 3). In the following table a new base practice that was added is represented in ***bold italics***.

### Table 3: Medi SPICE RM Base Practices for Establishing RM scope

|  |  |  |  |
| --- | --- | --- | --- |
| **Base Practice No:** | **Description** | **Specified in ISO/IEC** **15504-5?** | **Specified In the Medical device regulations?** |
| Man.5.BP1 | Determine the scope of risk management to be performed. | **Yes** | **Yes** |
| ***Man.5.BP1a*** | ***Define the scope of the strategy and include those life-cycle phases for which the strategy is applicable*** |  ***No*** | ***Yes – ISO 14971 Section 3.4(a)*** |

Table 4, provides a high level summary of the number of additional sub-practices that had to be added to the ISO/IEC 15504-5 RM process to achieve the Medi SPICE objectives. The table illustrates that there are 31 sub-practices within Medi SPICE RM. Thirty of these base practices are required within the medical device industry whereas only 8 are required within the ISO/IEC 15504-5 RM process. Only one of the seven ISO/IEC 15504-5 base practices fully satisfies the requirements of the associated Medi SPICE RM practice (i.e BP 4: Analyse Risks). Therefore, the mappings highlight that Medi SPICE needs to be more comprehensive in its coverage of the RM process than ISO/IEC 15504-5 in order to satisfy the regulatory requirements of the medical device industry.

### Table 4: Summary of Medi SPICE RM Process

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| --- | --- | --- | --- |
| **Practice** | **ISO/IEC 15504-5 Sub-Practices** | **ISO/IEC 15504-5 Sub-Practices required to meet regulatory medical device requirements** | **Additional Sub-Practices required to meet regulatory medical device requirements** |
| **BP1: Establish risk management scope** | 1 | 1 | 1 |
| **BP2: Define risk management strategies** | 1 | 1 | 11 |
| **BP3: Identify risks** | 2 | 1 | 3 |
| **BP4: Analyse risks** | 1 | 1 | 0 |
| **BP5: Define and Perform risk treatment actions** | 1 | 1 | 5 |
| **BP6: Monitor risks** | 1 | 1 | 2 |
| **BP7: Take Preventative or Corrective action** | 1 | 1 | 1 |
| **Total** | **8** | **7** | **23** |

With respect to the practices of the Medi SPICE RM process, we discovered that following the base practices of the ISO/IEC 15504-5 RM process will at best, only partially meet the regulatory requirements of the medical device industry in relation to RM. For RM, the existing ISO/IEC 15504-5 specification of outcomes and base practices can be carried over, with the extension mentioned above into the Medi SPICE framework.

**5.** **Conclusions and Future Work**

In developing Medi SPICE our approach is to examine all of the ISO/IEC 15504-5 processes but to focus initially on the 16 processes that will require the most amendments to satisfy the medical device regulatory requirements. Our vision is to provide a framework that will encourage medical device companies to distance themselves from the concept of developing the software first and then completing the necessary documentation that is required to achieve FDA compliance, to instead pursuing a continuous SPI path that will produce more efficient software development and safer medical devices. In this paper we have included a summary of the Medi SPICE RM process as this is a key process within the medical device industry and therefore requires comprehensive coverage. However, upon development of other Medi SPICE processes we may discover that the associated ISO/IEC 15504-5 base practices will more than satisfy the regulatory medical device requirements and in these cases the medical device industry may be able to adopt some of the additional ISO/IEC 15504-5 sub-practices to increase the efficiency of that process.

We also plan to ensure that a medical device company adopting Medi SPICE processes will also perform all the base processes that are defined within the ISO/IEC 15504 Part 7 Examplar Organisational Maturity Model [18].

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