Piloting MDevSPICE® - the Medical Device Software Process Assessment Framework

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ABSTRACT

Software development companies moving into the medical device domain often find themselves overwhelmed by the number of regulatory requirements they need to satisfy before they can market their device. Several international standards and guidance documents have been developed to help companies on their road to regulatory compliance but working their way through the various standards is a challenge in itself. In order to help software companies in the medical device domain, we have developed an integrated framework of medical device software development best practices called MDevSPICE®. This framework integrates generic software development best practices with medical device standards' requirements enabling consistent and thorough assessment of medical device processes.

MDevSPICE® can be used by software companies evaluating their readiness for regulatory audits as well as by large medical device manufacturers for selecting suitable software suppliers.

The MDevSPICE® framework consists of a process reference model, a process assessment model, an assessment method, and training and certification schemes. The framework has been validated using expert reviews and through MDevSPICE® assessments in industry. In this paper, we describe the MDevSPICE® process assessment framework focusing on its benefits and significance for the medical device manufacturing community as learned from MDevSPICE® assessments conducted to date.

Categories and Subject Descriptors

D.2.0 [**Software Engineering**]: General - *Standards.*

General Terms

Management, Measurement, Documentation, Performance, Reliability, Standardization.

Keywords

MDevSPICE®, process assessment framework, medical device regulation, medical device software.

1. INTRODUCTION

Safety-critical software systems are increasingly affecting our lives and welfare as more and more software is embedded into medical devices, cars and airplanes each day. New approaches and international standards are being developed to ensure the safety of these systems before they are delivered. In order to market a medical device, for example, the manufacturer has to satisfy a number of regional regulatory requirements commonly achieved by following international standards and guidance issued by international standardizing bodies and regional regulatory authorities. To help software companies in the medical device domain in their attempt to reach regulatory compliance, we have developed an integrated framework of medical device software development best practices called MDevSPICE®. This framework integrates generic software development best practices with medical device standards' requirements enabling robust software process assessments. The "SPICE" in MDevSPICE® reflects its foundation in the ISO/IEC 15504 (SPICE) series of standards for process assessment. Through validating the MDevSPICE® framework we provide evidence that process assessment can also help increase a company's readiness for regulatory audits. Furthermore, the MDevSPICE® framework can also help larger medical device manufactures when selecting suitable software suppliers.

In this paper we describe the development of the MDevSPICE® framework by first explaining the regulatory requirements medical device software development companies face before they are able to market their devices and how this motivated us to develop the MDevSPICE® framework. We will then focus on the lessons we learned when validating the framework in expert reviews and in industry through MDevSPICE® pilot assessments. We finish the paper with a brief summary about the benefits of using process assessment in safety-critical domains such as the medical device domain in order to better prepare for regulatory audits as well as to increase the safety and quality of the developed products.

2. REGULATORY REQUIREMENTS FOR SOFTWARE IN THE MEDICAL DEVICE DOMAIN

2.1 Medical devices and regulation in the EU and US

A medical device can consist entirely of software or have software as a component of the overall medical device system. In order to be able to market a medical device within a particular region it is necessary to comply with the associated regulatory demands. Two of the largest global bodies responsible for issuing and managing medical device regulation belong to the central governing functions of the US and EU. In the US, the Food and Drug Administration (FDA) issues the regulation through a series of official channels, including the Code of Federal Regulation (CFR) Title 21, Chapter I, Subchapter H, Part 820 [1]. Under US regulation, there are three medical device safety classifications:

Class I, Class II and Class III. The medical device safety classification is based on the clinical safety of the device. Class I devices are not intended to support or sustain human life, and may not present an unreasonable risk of harm. A thermometer is a Class I device. Class II devices could cause damage or harm to humans. An example of a Class II medical device is a powered wheelchair. Class III medical devices are usually those that support or sustain human life, and are of significant importance in the prevention of human health impairment. An example of a Class III device is an implantable pacemaker. All implantable devices are Class III medical devices as the surgery required carries with itself additional high risks from anesthesia and possible infections that go beyond the safety risks of the medical device.

In the EU, the corresponding regulation is outlined in the general Medical Device Directive (MDD) 93/42/EEC [2], the Active Implantable Medical Device Directive (AIMDD) 90/385/EEC [3], and the *In-vitro* Diagnostic (IVD) Medical Device Directive 98/79/EC [4] - all three of which have been amended by 2007/47/EC [5]. Similarly to the US, the EU device safety is also based on clinical safety of the device embodying similar classifications and limitations, where Class I in the EU corresponds to Class I in the US, Class IIa and IIb to Class II, and Class III to Class III.

2.2 International standards in the medical device domain

A further safety classification applies to the software in medical devices as outlined in IEC 62304:2006 (IEC 62304 from hereon) [6], where the safety classification is determined based on the worst possible consequence in the case of a software failure. In the case of failure of software that is of safety Class A no injury or damage to health of a patient can occur. When software of safety class B fails, injury may occur but it is not serious or life-threatening. Class C medical device software is of highest risk and in the case of failure of such software death or serious injury can happen. Depending on the functionality of software within the medical device, the software safety classification may vary from the overall medical device safety class. When software is of critical functionality of the medical device, it will carry the same classification as the device, i.e. Class C software in Class III device. The safety classification of software may be lower but cannot be higher than the overall medical device safety class, e.g. software of safety Class B may be embedded in Class III device but there cannot be software of safety Class C in a Class I or Class II device.

Medical device manufacturers in the US as well as in EU must satisfy quality system requirements to market their developed devices. In the medical device domain, ISO 13485:2003 (ISO 13485 from hereon) [7] outlines the requirements for regulatory purposes from a Quality Management System (QMS) perspective in medical device domain. ISO 13485, which is based on ISO 9001 [8], can be used to assess an organization's ability to meet both customer and regulatory requirements in the medical device domain. ISO 13485 does not, however, include requirements for software development. IEC 62304, which can be used in conjunction with ISO 13485, does offer a framework for the lifecycle processes necessary for the safe design and maintenance of medical device software. As a basic foundation, IEC 62304 assumes that medical device software is developed and maintained within a QMS such as ISO 13485, but does not require an organization to be certified against ISO 13485. Therefore, IEC 62304 can be considered to be a software development specific supplement to ISO 13485, similarly to ISO 90003 for ISO 9001.

IEC 62304 is based on ISO/IEC 12207:1995 [9] which although a comprehensive standard for software development lifecycle processes has effectively been decommissioned following the publication of the more extensive ISO/IEC 12207:2008 [10]. Furthermore, other developments in the ISO and IEC communities for software development, such as ISO/IEC 15504 [11], have provided significant additional levels of software process detail to support ISO/IEC 12207:2008. IEC 62304 is a critical standard for medical device software developers as it is the only standard that provides recommendations for medical device software implementations based on the worst consequences in the case the software failure causing hazards. Furthermore, for general medical device risk management, IEC 62304 is used in conjunction with ISO 14971 [12] and IEC 80002-1 [13] that provides guidance on the application of ISO 14971 for software development. As IEC 62304 considers a medical device system to consist of software as its sub-system, the system or product level requirements are not included within IEC 62304 but instead within the medical device product standard IEC 60601-1 [14]. Due to the increasing importance of usability of devices within the medical device industry, organizations should also adhere to the medical device usability engineering process requirements outlined in IEC 62366 [15]. When Medical Device Directives were amended in 2007 [5], it allowed standalone software to be defined as a medical device in its own right. Previously, software had always been seen as a subsystem embedded in a medical device. This amendment revealed a gap in international standards as none of the published standards were addressing the concerns for standalone software as a medical device. Today, IEC CD 82304-1 [16] applies to the safety of health software that is designed to operate on general purpose IT platforms and that is intended to be placed on the market without dedicated hardware, e.g. iPad applications.

2.3 FDA and their guidance documents

All companies planning to market a medical device in the United States need to register their product with the US FDA. Most Class I devices can be self-registered but most Class II devices require a 510(k) submission. For Class III devices, a Pre-Market (PMA) submission is needed. To support manufacturers in addressing the relevant guidance, the FDA has issued an overview of their guidance documents for medical device manufacturers and software developers [17].

The FDA Guidance on Premarket Submissions [18] provides guidance and recommendation for premarket submissions for software devices, including standalone software applications and hardware-based devices that incorporate software. Premarket submission includes requirements for software-related documentation that should be consistent with the intended use of the Software Device and the type of submission. In general terms, the medical device manufacturer needs to describe the following

in the premarket submissions: a) the design of the device, b) documentation about the implementation of that design, c) demonstration how the device was tested, d) how hazards were appropriately identified and risks effectively managed, e) how traceability is established between design, implementation, testing and risk management.

The FDA Guidance on Off-The-Shelf Software Use in Medical Devices [19] was published in 1999 with the purpose of describing the information that should be provided in a medical device application that uses off-the-shelf (OTS) software. Many of the principles outlined in this guidance document may also be helpful to device manufacturers in establishing design controls and validation plans for use of off-the-shelf software in their devices.

The FDA General Principles of Software Validation [20] outlines general validation principles that the FDA considers to be applicable to the validation of medical device software or the validation of software used to design, develop, or manufacture medical devices. This guidance describes how certain provisions of the medical device Quality System regulation apply to software. The scope of this guidance is somewhat broader than the scope of validation in the strictest definition of that term. Planning, verification, testing, traceability, configuration management, and many other aspects of good software engineering discussed in this guidance are important activities that together help to support a final conclusion that software is validated.

2.4 Medical device software standards vs generic software standards

Numerous different medical device standards and regulations now exist, some of which are interlinked with generic software development standards and others which are mostly independent. The dominant medical device software standards such as IEC 62304 are not yet aligned with the approach adopted in the general software development standards community since the 1995 publication of ISO/IEC 12207. One significant change in this respect has been the introduction of a harmonized approach to process description (as defined in ISO/IEC 24774 [21]) which involves the identification of core process outcomes that can later be harnessed to develop a process assessment method. A further significant change relates to the movement in the general software development standards community (and in other safety-related domains) to include a software process improvement dimension that can be instrumental in guiding software development organizations towards the required process targets. In effect, the medical device standards have not kept up with the changes that have been made to the general software development standards. There are several reasons why the medical device standards lag the updates to the general software development standards, (perhaps) most importantly the IEC stability period during which adopted harmonized standards are not to be changed unless the proposed changes are necessary in terms of safety. With the expanding role of software in medical devices, there is a case to be made for introducing the accumulated up-to-date wisdom in the general software development standards into the medical device software development specific standards in a uniform fashion – and work in this direction should not wait for the IEC stability period to come to an end, but rather proceed in the interim period.

Furthermore, the challenge that software development companies in the medical device domain face when they want to market a device is in the adherence to a large number of regulatory requirements specified in various international standards (that can often become overwhelming). In order to help these companies better prepare for demanding and costly regulatory audits, we developed the MDevSPICE® framework. MDevSPICE® includes requirements from the previously mentioned standards and guidance documents rendering the task of regulatory compliance much less complex. Following is a detailed description of the development of the MDevSPICE® framework that integrates the requirements from various international medical device standards and guidance documents with the generic software development best practices while providing a possibility to assess processes.

3. DEVELOPMENT OF THE MDEVSPICE® FRAMEWORK
3.1 MDevSPICE® Process Reference Model

A process reference model (PRM) describes a set of processes in a structured manner through a process name, process purpose and process outcomes where the process outcomes are the normative requirements the process should satisfy to achieve the purpose of the process. In order to develop a PRM that integrates requirements from various standards allowing the processes to be evaluated in terms of their achievement of their purpose statements, we followed the format of the process description illustrated in ISO/IEC 24774 [21]. With that in mind, we first mapped and integrated the requirements from ISO/IEC 12207:2008 and IEC 62304 into what today is called the Process Reference Model for IEC 62304 (but which also reflects the updates to ISO/IEC 12207 from the 1995 to the 2007 version). A systematic approach of memoing and constant comparison, which is based on the principles of Grounded Theory [22] was followed when developing the PRM, further details of which are to be found in [23]. The approach of memoing and constant comparison is suitable for systematically integrating information from various different sources [24]. The Process Reference Model of IEC 62304 was published in June 2014 as IEC TR 80002-3 [25].

While IEC 62304 describes only the software life cycle processes, additional processes should be in place for system development in the case where software is not embedded as part of an overall medical device. These additional processes were derived from ISO/IEC 12207:2008. Design and development related requirements from ISO 13485 and ISO 14971 were also added to the MDevSPICE® Process Reference Model. Both ISO 13485 and ISO 14971 are *de facto* standards for medical device software organizations. ISO 13485 requirements are primarily related to system level processes and ISO 14971 is concerned with risk management (and therefore aligned with the Software Risk Management process of the PRM.

ISO 13485 requirements were integrated into the MDevSPICE® PRM through relevant new Process Outcomes where no corresponding ones already existed, or as Notes where corresponding Process Outcomes were already in place. Some of the QMS requirements target higher Capability Levels, in which case the requirements were related to Generic Practices Process Attribute (PA) 2.1 (e.g. on allocating resources) or to PA 2.2 (e.g. on documentation) on Capability Level 2. The outcomes or notes derived from ISO 13485 are highlighted in the MDevSPICE® PRM to visualize the source standard.

ISO 14971 distributes the risk management related requirements across all software life cycle processes. To avoid major duplication, the risk management requirements were kept only within the Software Risk Management process of the main body of the PRM. Instead of distributing these requirements across life cycle processes, a table was added in the Annex of the PRM that lists the specific risk management requirements for each software life cycle process. These requirements need to be added to the selected software life cycle processes for process assessment in the case where the process assessment will not include the Software Risk Management process in its entirety.

The final MDevSPICE® PRM consists of 23 processes of which 10 are system life cycle processes, 8 are software life cycle processes and the remaining 5 support both the system and life cycle processes as can be seen in Figure 1.
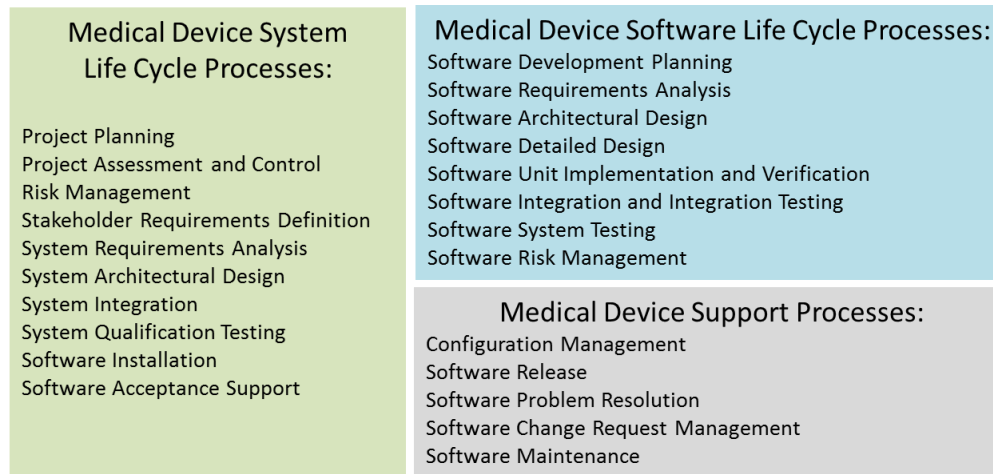
MDevSPICE® PAM, similar to ISO/IEC 15504-5 (SPICE) [27], has two dimensions – a process dimension and a capability dimension. The process dimension lists three groups of processes from various models and standards, i.e. systems life cycle processes, software life cycle processes and support processes. Each process is described in terms of a Process Name, Process Purpose, Process Outcomes, Base Practices, Work Products and Work Product Characteristics. As already noted, Process Outcomes are the normative requirements within a process, the achievement of which will allow satisfying the Process Purpose statement. Base Practices are informative activities that illustrate one possible way (workflow) to achieve the corresponding Process Outcomes. Work Products are artefacts that are either produced or used by the Base Practices, and support the achievement of the Process Outcome. Each Work Product is further described in terms of its content called the Work Product Characteristics. In the case of the MDevSPICE® PAM, some of these Work Products are normative as they are based on the requirements derived from IEC 62304, ISO 14971 or ISO 13485. Similarly, their content may have been specified in these standards, and if that is the case, this information has been carried forward to the Work Products Characteristics of the MDevSPICE® PAM.

Figure 2 below describes the different sources of the MDevSPICE® PRM and PAM. The MDevSPICE® PRM is based on IEC 62304, ISO/IEC 12207:2008, ISO 14971 and ISO 13485. The MDevSPICE® PAM then extends this PRM with base practices and work products, some of the latter also being normative as they are described in IEC 62304, ISO 14971 or ISO 13485 as requirements. Where process outcomes are derived from ISO/IEC 12207:2008, their corresponding base practices and work products are derived from ISO/IEC 15504-5. Where process outcomes are derived from ISO 14971, their corresponding base practices are derived from IEC 80002-1. In addition to these sources, FDA guidance on premarket submissions, software validation and off-the-shelf software have been added to the informative base practices where the base practice did not already address the requirements of the corresponding FDA guidance. Product safety requirements have been added to the MDevSPICE® PAM from both IEC 60601-1 and IEC CD 82304-1, while the usability engineering requirements have been incorporated from IEC 62366.

The capability dimension of the MDevSPICE® PAM is derived directly from ISO/IEC 15504 together with the Capability Levels, Process Attributes, Generic Practices, Generic Resources and Generic Work Products.
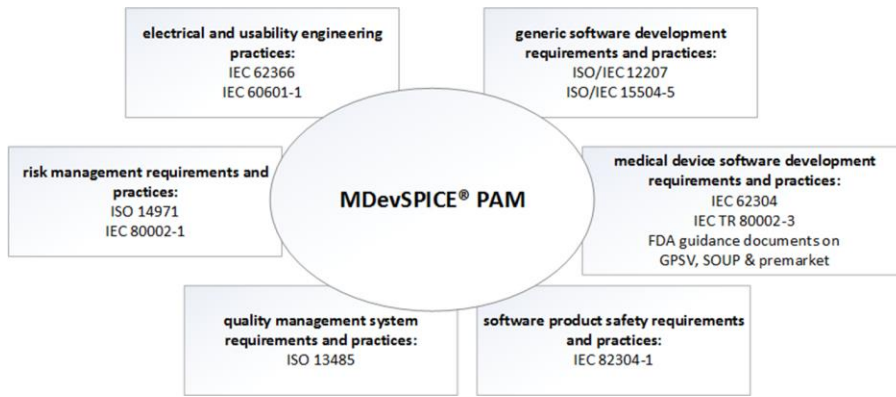
Medical Device System Life Cycle Processes:

Project Planning
Project Assessment and Control
Risk Management
Stakeholder Requirements Definition
System Requirements Analysis
System Architectural Design
System Integration
System Qualification Testing
Software Installation
Software Acceptance Support

Medical Device Software Life Cycle Processes:

Software Development Planning
Software Requirements Analysis
Software Architectural Design
Software Detailed Design
Software Unit Implementation and Verification
Software Integration and Integration Testing
Software System Testing
Software Risk Management

Medical Device Support Processes:

Configuration Management
Software Release
Software Problem Resolution
Software Change Request Management
Software Maintenance

Figure 1. Processes of MDevSPICE® PRM

The MDevSPICE® PRM was then extended with additional elements to create a process assessment model (PAM) described in greater detail in the following section.

3.2 From process reference model to process assessment model

Process assessment provides software development companies with a capability profile of their development processes, their strengths and weaknesses in relation to the normative requirements of a model with the aim to improve processes and close the discovered gaps. While the generic software development domain is moving away from best practice implementation [26] and towards agile and scrum practices, companies operating in safety-critical sectors such as the medical device domain have to demonstrate the compliance of their design and development processes with regulatory requirements together with the evidence of detailed documentation.

The aim of the MDevSPICE® PAM is to provide a comprehensive model for assessing the software and systems development processes against the widely recognized medical device regulations, standards and guidelines that a software development organization in the medical device domain has to adhere to. The

Figure 2. Standards integrated in the MDevSPICE® PAM

In order to scope an MDevSPICE® assessment, various requirements need to be taken into account, including the classification of the medical device software and the standards and guidance documents to be considered. With the exception of IEC 62304, all other integrated international standards and guidance documents can be scoped or de-scoped from the assessment. MDevSPICE® process assessments provide a detailed overview of the medical device software development processes together with any gaps discovered to the normative requirements of the MDevSPICE® model. MDevSPICE® process assessment results describe the capability of each assessed process as well as the compliance to any of the chosen standards' requirements that are in the MDevSPICE® PAM.

3.3 From process assessment model to process assessment framework

A process reference model and a process assessment model are not enough to provide a solid basis for conducting new domain-specific process assessments in a repetitive and consistent manner. Therefore, the MDevSPICE® process assessment method was developed to describe precisely how an MDevSPICE® process assessment should be conducted, (as illustrated in Figure 3). The MDevSPICE® training and assessor certification schemes provide the knowledge and structure that the certified MDevSPICE® assessors need to conduct MDevSPICE® assessments.

There are various roles involved in an MDevSPICE® assessment – the key roles are that of a Sponsor, an MDevSPICE® Principal or Lead Assessor and the other MDevSPICE® assessor(s). The latter two roles form an Assessment Team. The assessment Sponsor is either a person or an entity that requests the performance of an MDevSPICE® assessment and who provides financial and other resources for the assessment. The assessment Sponsor can be either internal to the assessed organization or external, e.g. when a software supplier's process capability is to be determined. According to the MDevSPICE® Assessor Certification Scheme, there are three types of assessors: a Principal MDevSPICE® assessor, a Lead MDevSPICE® assessor and an MDevSPICE® assessor. An MDevSPICE® Lead Assessor who can perform 3rd party assessments is called the Principal assessor.

The Assessment Team members must have a firm understanding of the MDevSPICE® Process Reference Model (PRM), the MDevSPICE® Process Assessment Model (PAM) and the related Medical Device standards and regulations. The Assessment Team must also have an understanding of the organizational unit, the organizational culture and the different geographic locations involved in the assessment. This understanding plays a crucial role in the overall execution of the assessment.

MDevSPICE® process assessments are typically performed to provide a gap analysis and/or to establish the strengths and weaknesses of the organization's processes while evaluating the capability of these processes against specific requirements. An MDevSPICE® process assessment can be performed as a) a process evaluation before regulatory audits, b) a gap analysis as a part of an internal process improvement program, and/or c) a capability determination of specific processes to determine the suitability of an organization in supplying software for medical devices (where the devices may be manufactured by another organization).
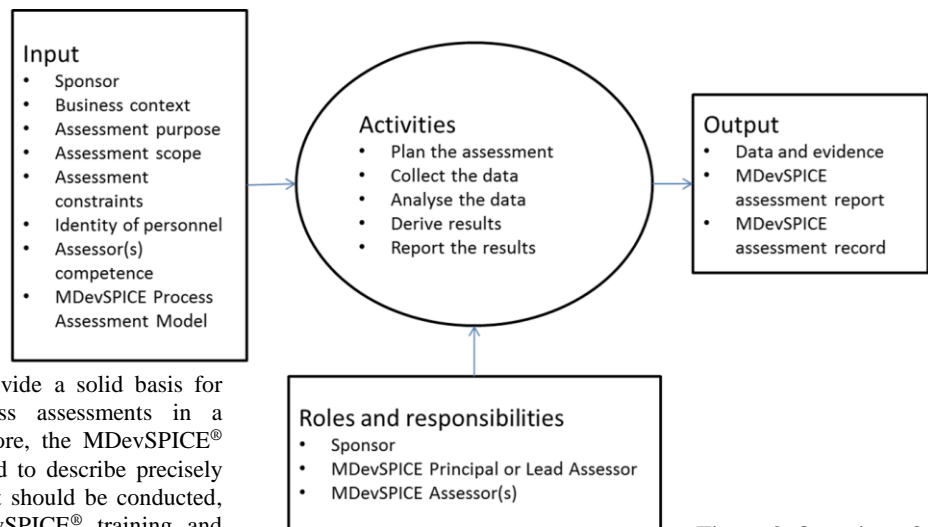

Figure 3. Overview of the MDevSPICE® assessment method

The MDevSPICE® process assessment method has 5 main phases (refer to the activities in Figure 3) from planning the assessment to reporting the results. The amount of evidence required in a process assessment depends on the purpose and the class of the assessment. As a result of an MDevSPICE® process assessment, the assessed company is provided with a detailed assessment report about their processes. The main components of a process assessment output are the process profiles, which provide a structured representation of an individual process capability. These process profiles are then compared with the target profiles defined prior to the assessment based on the organization's expectations and constraints. This enables a clear understanding of the gaps to be covered in order to reach the target profile.

4. VALIDATION OF THE FRAMEWORK

The MDevSPICE® framework has been validated in various stages of its development by different parties through both international expert review and industrial trials. The foundation of the MDevSPICE® PAM, IEC TR 80002-3 (the development of which was led by the authors), was published after several iterations of development and analysis by the standardization working group responsible for the publication of IEC 62304 (i.e. ISO/IEC Sub-Committee 62A, Joint Working Group 3). An international standard is published only after the national delegates of the standard's working group have agreed on every detail of that standard. As a result of this validation, one of the important lessons concerned the use of terminology in the MDevSPICE® PAM. Namely, the language and terminology used in the medical device software domain is slightly different from that used within generic software development. The terminology adopted in the MDevSPICE® PAM is in line with that used within the standards and guidance documents used within the medical device software domain in order to enable easier adoption of the new model within the domain.

In addition to working with the international medical device standards community, the MDevSPICE® PAM has also been developed together with and analyzed by experts in process assessment working group 10 of ISO/IEC Joint Technical Committee 1, Sub-Committee 7, responsible for the development and maintenance of the series of process assessment standards. These standards are currently being revised from ISO/IEC 15504 series to ISO/IEC 330xx series of standards. MDevSPICE® framework keeps abreast of these updates as well as with the updates of any other standard and guidance document information from which is contained in the MDevSPICE® framework.

Upon successful completion of international expert review, the MDevSPICE® process assessment framework was then validated in the medical device software industry through pilot assessments over the past two years. MDevSPICE® process assessments were conducted in different types of organizations: (1) a small software company wishing to supply software to a large medical device manufacturer who wants them to demonstrate that they are capable of developing safe medical device software and provide the medical device manufacturer with a feeling that they will not jeopardize the safety of their overall medical device or the reputation of their organization;(2) three different assessments (across a 2 year period) were performed in two different international sites of a multinational medical device manufacturer who wants to ensure that they are incorporating best practices within their software development processes to not only achieve regulatory compliance but also reduce the likelihood of recalls through developing better quality and more robust software; (3) a software development company seeking to achieve regulatory compliance against IEC 62304 so that they can become medical device software suppliers; and (4) a large automotive manufacturer experienced in developing safety-critical embedded automotive software now wishing to also develop embedded medical device software.

5. DISCUSSION – LESSONS LEARNED

As a result of the MDevSPICE® pilot assessments we have witnessed different types of needs in different companies. We can categorize these companies based on their position in and compliance to regulatory requirements in the medical device domain – first, there are the software companies that want to enter the medical device domain. They either require knowledge and information about the regulatory requirements they have to satisfy before they can market their device, or they want detailed instructions in terms of design, development and maintenance of medical device software. Second, there are the large medical device companies who already market some of their developed devices. They require help either in preparation for regulatory audits for new devices under development, or to improve their existing software development processes to enable higher quality software therefore reducing the risk of recalls in order to become or stay leaders in the market.

In order for the software developers entering the medical device domain to market their devices they have to start by implementing a Quality Management System including a Risk Management process, which involves adopting ISO 13485 and ISO 14971.

Companies with QMS in place but unsure that their software development is compliant with the requirements of ISO 13485 and IEC 62304 stand to derive great benefit from undertaking an MDevSPICE® process assessment. As a result of such process assessment, the company not only obtains a detailed overview of their development processes but gains an understanding of the gaps to be addressed in order to obtain compliance against one of more of the medical device software standards (e.g. IEC 62304, IEC 80002-1 etc.). Similarly, existing medical device manufacturers who want to ensure that they can pass a regulatory audit can use a process assessment to discover any possible weaknesses in their development processes. The findings from a process assessment contain a detailed list of strengths, weaknesses and associated process improvement recommendations that should be implemented in order to achieve a particular goal e.g pass an IEC 62304 audit or satisfy FDA guidance on software validation or reach MDevSPICE® capability level 3 thus maximizing the possibility of safe product implementation.

Medical device manufacturers who want to remain market leaders must ensure that their devices are safe and will not be recalled due to a software fault. Large medical device manufacturers therefore reduce the risk of recalls through adopting the latest best practice techniques and standards. Such companies will have IEC 62304 compliant software development processes and this is where the capability dimension of MDevSPICE® becomes important. These companies can still improve the planning, management and implementation of their processes together with the input and output documentation of these processes, as well as standardizing their development processes across their development department. Significantly, such companies also want to ensure that their software suppliers are also adopting similar quality software development processes and an MDevSPICE® assessment can be used to evaluate their suppliers' processes.

A key finding from performing the pilot MDevSPICE® assessments was that the companies derived significant value not just from obtaining feedback in a textual manner but also in a graphical representation across each of the various medical device standards within MDevSPICE®. Additionally, when conducting MDevSPICE® assessments it was important to follow the natural order of the software development lifecycle. Finally, due to the fact that an MDevSPICE® assessment covers multiple standards it was important that a scripted set of questions were followed to ensure that all intended standards' requirements were adequately covered.

6. SUMMARY

This paper describes the benefits process assessments can bring to companies in a safety-critical domain. Safety-critical domains are characterized by heavy regulatory demands that companies have to adhere to before they can market their devices. Regulatory audits are conducted regularly to evaluate these companies and the safety of their developed devices. Process assessments can help medical device software developers to better prepare themselves for resource-demanding and costly audits. For that purpose, we have developed a medical device software process assessment framework called MDevSPICE® that integrates requirements from all the major relevant international standards and guidance documents of the medical device domain. We have illustrated the framework in this paper and elaborated on the lessons we learned when validating the framework in industry, resulting in a thorough understanding of the benefits that process assessments bring to safety-critical domains.

Having assembled a multi-disciplinary internationally recognized team, the MDevSPICE® framework has been systematically and carefully developed in the Regulated Software Research Center based at Dundalk Institute of Technology. Many years of sustained research and development have produced the MDevSPICE® framework which has - for the first time – consolidated the various disparate medical device standards and guidance into one single location. MDevSPICE® has furthermore integrated the accumulated best practices from generic software development and provided a robust assessment vehicle as a means to evaluating process capability. This represents a significant step forward for medical device software development as it reduces the complexity of various standards and guidance into one single repository while also enabling a robust investigation of process implementation. Over the coming years, medical device manufacturers should derive significant benefit from these advancements. The first step along this road will involve the training and certification of MDevSPICE® Assessors – an activity that is due to commence

ACKNOWLEDGMENTS

7. REFERENCES

[1]		FDA. *Chapter I - Food and drug administration, department of health and human services subchapter H - Medical devices, Part 820 - Quality system regulation*. Available from: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820.

[2]		*Directive 93/42/EEC of the European Parliament and of the Council concerning medical devices*. 1993. European Commission, Brussels, Belgium.

[3]		*Council directive 90/385/EEC on active implantable medical devices (AIMDD)*. 1990. Brussels, Belgium.

[4]		*Directive 98/79/EC of the european parliament and of the council of 27 october 1998 on in vitro diagnostic medical devices*. 1998. Brussels, Belgium.

[5]		*Directive 2007/47/EC of the European Parliament and of the Council concerning medical devices*. 2007. EC: Brussels, Belgium.

[6]		*IEC 62304: Medical Device Software - Software Life-Cycle Processes*. 2006. IEC: Geneva, Switzerland.

[7]		*ISO 13485: Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes*. 2003. ISO: Geneva, Switzerland.

[8]		*ISO 9001:2000 - Quality Management Systems - Requirements*. 2000. Geneva, Switzerland.

[9]		*ISO/IEC 12207:1995 - Information Technology - Software Life-Cycle Processes*. 1995. ISO/IEC: Geneva, Switzerland.

[10]		ISO/IEC. 2008. *ISO/IEC 12207:2008 - Systems and Software Engineering - Software life cycle processes*, ISO/IEC: Geneva, Switzerland.

[11]		ISO/IEC 15504-2. 2004. *Information technology - Software process assessment - A reference model for processes and process capability*, in *15504*.

[12]		*ISO 14971 - Medical Devices - Application of Risk Management to Medical Devices* 2009. ISO: Geneva, Switzerland.

[13]		*IEC TR 80002-1 - Medical Device Software - Part 1: Guidance on the Application of ISO 14971 to Medical Device Software*. 2009. IEC: Geneva, Switzerland.

[14]		*IEC 60601-1 - Medical electrical equipment – Part 1: General requirements for basic safety and essential performance* 2005. IEC: Geneva, Switzerland.

[15]		*IEC 62366 - Medical devices - Application of usability engineering to medical devices*. 2007. IEC: Geneva, Switzerland.

[16]		*IEC 82304-1: Health software -- Part 1: General requirements for product safety*. 2012. IEC: Geneva, Switzerland.

[17]		FDA. 2015. *Guidance Documents (Medical Devices and Radiation-Emitting Products)*.

[18]		*FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*. 2005. FDA: USA. 20.

[19]		*FDA's Guidance for industry, FDA reviewers and compliance on - Off-The-Shelf Software Use in Medical Devices*. 1999. FDA: USA. 26.

[20]		*FDA's General Principles of Software Validation; Final Guidance for Industry and FDA Staff*. 2002. FDA: USA. 43.

[21]		*ISO/IEC 24774 - Systems and Software Engineering - Life Cycle Management - Guidelines for Process Description*. 2010. Geneva, Switzerland.

[22]		Glaser, B. and Strauss, A. 1976. *The Discovery of Grounded Theory: Strategies for Qualitative Research*, ed. A.d. Gruyter. Hawthorne, NY, USA.

[23]		Lepmets, M., Clarke, P., McCaffery, F., Finnegan, A., and Dorling, A. 2014. *Development of a Process Assessment Model for Medical Device Software Development*, in *Industrial Proceedings of the 21st EuroSPI Conference*: Luxembourg. p. 2.25-2.35.

[24]		Clarke, P. and O'Connor, R.V. 2012. *The situational factors that affect the software development process: Towards a comprehensive reference framework.* Information and Software Technology. 54(5): p. 433-447.

[25]		*IEC TR 80002-3: Medical device software -- Part 3: Process reference model of medical device software life cycle processes (IEC 62304)*. 2014. IEC: Geneva, Switzerland.

[26]		Lepmets, M., O'Connor, R., Cater-Steel, A., Mesquida, A.L., and McBride, T. Year. *A Cynefin based approach to process model tailoring and goal alignment*. in *Proceedings of*

the 9th International Conference on the Quality of Information and Communications Technology (QUATIC). Portugal: IEEE Computer Society.

[27]   ISO/IEC 15504-5. Information technology - process assessment - Part 5: an exemplar process assessment model. 2012.