This is the Post-Print version of the published material

A Lightweight Software Process Assessment Approach based on MDevSPICE® for Medical Device Development Domain

Özden Özcan-Top[1], Fergal McCaffery[1,2]

[1]Regulated Software Research Centre & Lero
Dundalk Institute of Technology, Dundalk, Ireland
[2]STATSports Group, Dundalk, Ireland
ozden.ozcantop@dkit.ie, fergal.mccaffery@dkit.ie

Abstract. Software process improvement is challenging in the medical device development domain, as significant constraints exist such as ensuring conformance to regulations while improving software quality. The regulations that medical products are subject to may be overwhelming for organisations as a variety of international standards have to be implemented in order to address regulatory compliance. MDevSPICE® is a framework developed to overcome this challenge by integrating different international regulatory standards' requirements with generic software development best practices. Keeping the complexity of the domain in mind, the formal process assessments performed based on MDevSPICE® are highly detailed and require significant resource and effort investment. With the MDevSPICE® lightweight software process assessment approach, we aim to obtain maximum benefit from an assessment within a limited time by assessing all processes within MDevSPICE®, specifying and presenting major issues in projects, prioritizing such issues and progressing to the improvement stage as early as possible. The approach has designed to be a solution to improve feedback time and motivation to move forward for software process improvement actions. In this experience paper, we describe the development of the lightweight MDevSPICE® assessment method and its implementation in four companies.

Keywords. Lightweight Assessment, Medical Device Software Development, Regulatory Requirements, Safety Critical, MDevSPICE®

1   Introduction

Systems developed in medical, automotive, military-aviation, food, nuclear, pharmaceutical and railway domains are significant parts of our daily lives and are subject to heavy regulatory demands due to their safety critical characteristics. This is particularly the case in the medical domain, where the purpose of the regulations is to ensure that developed systems will not harm patients.

Medical device manufacturers in the US as well as in the EU must satisfy the associated regulatory demands of the region that the device will be marketed in. A variety of international standards have to be implemented in order to ensure regulatory requirements for a medical device. Such standards include IEC 62304:2006 (software life cycle processes for medical device software) [1], ISO 13485:2003 (quality management system requirements) [2] and ISO 14971 (risk management) [3] but there are many more.

An integrated framework for medical device software development MDevSPICE® has been developed by one of the authors to assist software development organisations in the medical device domain to achieve regulatory compliance [4, 5]. MDevSPICE® integrates generic software development best practices with medical device standards' requirements enabling robust software process assessments to be performed against an organisation's current software development practices. Either self-assessments or assessments against a standard are important in terms of creating action plans for improvement [6]. These process assessments may be used in different ways: a) to ensure that the medical device software being developed by an organization conforms to regulatory software requirements for the industry which are across a spectrum of medical device standards (but defined in one place within MDevSPICE®) (before regulatory audits) b) to use as a guidance for process improvement activities, and c) to obtain support for action in developing better products.

In this experience paper, we present a light weight process assessment approach that allows practitioners to achieve significant results from the limited time that is available for performing an assessment. As part of this research we have performed MDevSPICE® based process assessments in four Irish software development companies, three of which are in medical device development domain. This approach was

developed in an iterative and incremental way with the experiences we had after each assessment and has been evolved as a result of learnings in each assessment.

The paper is structured as follows: In the next section, the MDevSPICE® framework is presented. Following this, we present the literature survey on software process assessment. In Section 4, we present the lightweight process assessment approach along with the development stages. Details of the implementation are also discussed in Section 4. Finally, an overall conclusion is presented.

2   MDevSPICE® Framework

MDevSPICE® has been developed with the purpose of reducing the demanding and costly overhead associated with preparing for regulatory audits. It is a process capability assessment model which supports the performance of medical device software process assessments in accordance with the requirements of ISO/IEC 33002:2015 [7].

It has been built upon a wide number of medical software development and software engineering standards some of which are 'IEC 62304:2006: Software life cycle processes for medical device development [1]'; 'ISO/IEC 12207:2008: Software life cycle processes' [8], 'ISO/IEC 33002:2015: Requirements for performing process assessment' [7], 'ISO 14971:2009: Application of risk management to medical devices'[3], and 'ISO 13485:2003: Medical devices — Quality management systems — Requirements for regulatory purposes' [2].

MDevSPICE® consists of two-dimensions: The first dimension is the process dimension in which the processes are defined and the second dimension is the capability dimension in which the process attributes constitute the process capability levels.

Each process in the process dimension is described in terms of a purpose statement. Satisfying the purpose statements of a process represents the first step in building a Level 1 process capability where the expected outcomes are observable. A list of specific outcomes are given in relation to process purpose statements. Each outcome is associated with at least one of the safety classes mentioned above which is a critical information to show mandatory outcomes to achieve the specific classes.

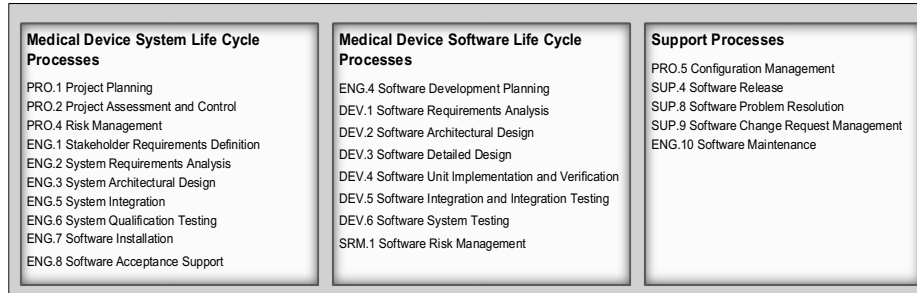The list of processes in MDevSPICE® process assessment model is given in Fig. 1.

Medical Device System Life Cycle Processes	Medical Device Software Life Cycle Processes	Support Processes
PRO.1 Project Planning	ENG.4 Software Development Planning	PRO.5 Configuration Management
PRO.2 Project Assessment and Control	DEV.1 Software Requirements Analysis	SUP.4 Software Release
PRO.4 Risk Management	DEV.2 Software Architectural Design	SUP.8 Software Problem Resolution
ENG.1 Stakeholder Requirements Definition	DEV.3 Software Detailed Design	SUP.9 Software Change Request Management
ENG.2 System Requirements Analysis	DEV.4 Software Unit Implementation and Verification	ENG.10 Software Maintenance
ENG.3 System Architectural Design	DEV.5 Software Integration and Integration Testing	
ENG.5 System Integration	DEV.6 Software System Testing	
ENG.6 System Qualification Testing	SRM.1 Software Risk Management	
ENG.7 Software Installation		
ENG.8 Software Acceptance Support		

Fig. 1. MDevSPICE® Processes

3   Literature Review on Formal and Lightweight Approaches to Software Process Assessment

In this section, we present the formal and lightweight software process assessment methods and the challenges in performing assessment associated with those methods over a literature review.

The first phase of method based software process improvement (SPI) studies is the process assessment where the purpose is to identify process gaps and weaknesses that exist within an organization or a project. These specified gaps and weaknesses play a significant role in success of improvement endeavors as they are used as a basis for improvement actions.

Software process assessment and improvement methods can be classified into two main categories: descriptive and prescriptive methods [9]. The descriptive methods aim to answer the question "how software is being actually developed?". Improvements are performed through gaining a thorough understanding of the current practices that are implemented in projects. There is no initial assessment or comparison with a pre-defined set of practices [10]. The prescriptive methods answer the question of "how software should be developed?" based on the best practices of the software industry [11]. Common SPI frameworks such as CMMI [12] and ISO/IEC 15504 (SPICE) [13] are also prescriptive models that are quite challenging to implement as they are too comprehensive [14].

Previously, the Regulated Software Research Center in DkIT published four light-weight software process assessment methods: Adept [15], Med-Adept [16], Med-Trace [17] and MDevSPICE-Adept [18]. Adept was developed in 2006 to assist small and medium sized Irish software organizations that have little or no experience of SPI [15]. It aims to diagnose weaknesses in a company's software processes and to provide a roadmap based on the business goals and specified weaknesses. The method uses a process assessment model adapted from CMMI® and ISO/IEC 15504 models. Twelve process areas may be assessed using the Adept Method, four of which are mandatory in an assessment: Requirements Management, Configuration Management, Project Planning, and Project Monitoring & Control. An onsite interview-based one day assessment is limited to six process areas using the Adept Method.

Med-Adept expends the Adept method for the medical device software development industry including processes for IEC 62304 [1]. In the overall, Med-Adept provides coverage of 11 CMMI® process areas, 12 ISO/IEC 15504-5 and 11 IEC 62304 processes. Med-Trace [17] was developed to analyze a mandatory component of medical device software development: traceability. The method aims to help evaluation and establishment of traceability linkages as there is no specific guidance within the medical device standards and documentation. A specific light-weight assessment model was required for MDevSPICE®. The aim when developing the MDevSPICE-Adept [18] method was to select a limited number of processes from out of the 23 processes that would be most beneficial and relevant to companies and to provide an onsite process assessment that lasted no longer than 2 days. Consequently, 11 processes were included in the method.

Pettersson et. al [14] published a lightweight software process assessment and improvement planning approach regardless of any specific framework to enable practitioners' to base improvement efforts on the issues that are the most critical for the specific organizations. The approach they suggested facilitates sampling of projects, roles and practitioners, and describes how to perform interviews and gives guidance on choosing an appropriate prioritization method.

Wiegers and Sturzenberger [19] discuss that CMM-based appraisals are quite expensive and time consuming and many companies find it difficult to perform these assessments regularly. They propose a mini-assessment method (MMA) to overcome this

challenge. The method proposes multiple options that are available for most assessment steps such as using questionnaires based on a) CMM practices, sub-practices, b) All CMM key practices, c) Institutionalization factors only. MMA doesn't include suggestions for follow-up action planning and action plan tracking activities or provide details on questionnaires used.

Success factors related to software process improvement (SPI) activities from a general perspective include management support, motivation and commitment of other employees, a systematic implementation strategy, standards and procedures, training and mentoring and experienced staff [6, 20-22] . It was shown by Rainer *et. al* that training and mentoring, and standards and procedures are considered as two factors having a major impact on SPI by low maturity companies. Mature companies having more detailed understanding of SPI additionally think that internal leadership, inspections, executive support, and internal process ownership have important impact on SPI success [21].

Although numerous studies have explored the success factors of SPI initiatives, there are no studies specifically exploring the success factors of software process assessment. However, new approaches to process assessment were suggested in the literature [23, 24]. Dyba and Moe mention that what is important for assessments are the identification of critical problems and establishment of improvement priorities [24]. In this study, a participative approach to assessment was adopted where data was collected from everyone in the organization and action planning was done by teams at all levels were suggested. Significant findings of this study which could be a guide for software process assessment could be summarized as follows:

- Involvement of different groups within the assessment increases the possibility of having multiple views and discovery of issues.
- Waiting too long before the assessment feedback session, may lead to a loss of SPI focus in the department/company.
- The data analysis and feedback session shouldn't be ended without identifying concrete areas for improvement.

- Holding a presentation for the assessment participants, provides motivation for the assessment, and ensures that everybody has the same understanding of the questions and the goals of the assessment.

Senior managers' active participation in assessment meetings is thought to add the necessary momentum to the initiative by Stelzer and Mellis [6], however, based on our opinions, this might cause pressure on the participants in assessment interviews and may prevent reveal of critical issues.

4   The Lightweight Software Process Assessment Approach

In this section, we describe the lightweight software process assessment approach developed based on MDevSPICE® for medical device software development domain. This approach aims to obtain maximum benefit from an assessment within a limited time by covering all processes within MDevSPICE®, specifying and presenting the major issues in projects, prioritizing these issues and starting improvement actions as early as possible.

4.1   The Structure of the Approach

Both formal and lightweight assessment approaches of MDevSPICE® are performed based on the high level flow shown in the BPMN diagram in Figure 2. The process starts with identification of assessment needs by sponsor. Based on the defined assessment needs, assessment scope, projects to be assessed, resources and team members are specified by the sponsor and lead assessor. The sponsor establishes the assessment plan and informs the assessment participants about the plan. Process and product artefacts are observed as evidence of achievement of base practices during interviews with process owners. During the next step, issues, challenges and strengths are reported by the assessment team. The report is validated during a findings reporting session where sponsor and process owners are involved.

The difference of the formal and lightweight assessment approaches lie in the three activities shown with orange in Figure 2: "Perform Interviews", "Observe Objective Evidence", and "Identify and Report the Issues Found".
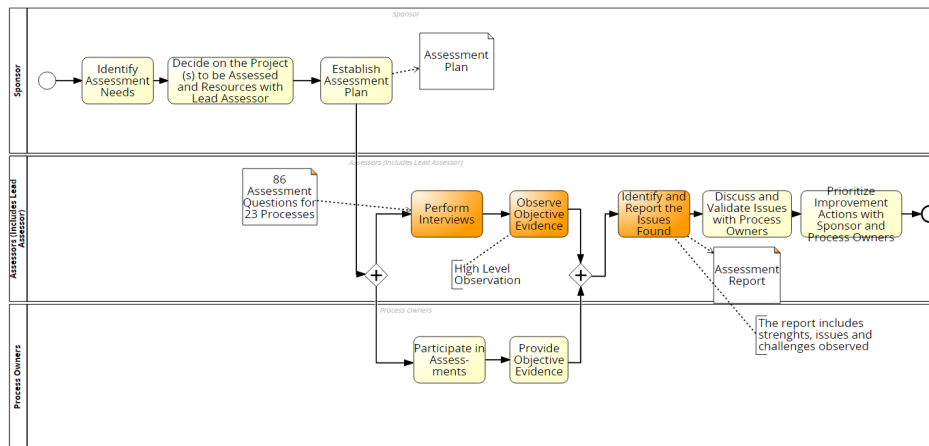
Fig. 2. High Level Flow of MDevSPICE® based Light Weight Process Assessment Approach

The "Perform Interviews" activity is a question and answer session where the responses from the process owners are recorded by assessors for analysis. A scripted question set is defined by assessors prior to this activity. The formal assessment approach of MDevSPICE® is so comprehensive that the scripted question includes 758 questions across 23 processes. Software Risk Management, Software Development Planning, Software Requirements, Software Unit Implementation and Testing and Software Architecture processes have larger number of questions, with 108, 78, 61, 51 and 43 respectively. As an example, it takes approximately 3 hours to discuss the Software Requirements Process having 61 questions with the process owners. A whole assessment takes approximately 37 hours. This requires having 6 business days of assessments back to back. For small organisations, such an uninterrupted dedication for assessments would not be possible. The assessment sessions usually take place with 2 to 3 hours sessions daily or 4 to 6 hours sessions on weekly basis. Such an implementation would result in a formal assessment being completed in months and prevent a rapid start to improvement activities.

With the motivation to reduce SPI initiation and to capture as many as issues possible within a limited time, we have updated the question set mentioned above to include a total of 86 questions for the 23 processes.

Question examples from the Software Risk Management process are shared in Table 1 and Table 2 to show how detailed questions differ from the lightweight questions:

Table 1. Software Risk Management Process Formal Question & Sub-Questions for Base Practice #1

SRM.1.BP1.Q1: Describe how you identify software items that can contribute to hazardous situations?
Do you identify hazardous situations that can arise as a direct result of software failures? [Class: B, C]
Do you identify hazardous situations that can arise as a result of failures of risk control measures implemented in software? [Class: B, C]
Do you document software items contributing to hazardous situations in the risk management file? [Class: B, C]
Where do you identify software items as contributing to hazardous situations, identify the potential causes of the contribution. [Class: B, C]
Do you identify any non-specified SOUP software (e.g. word processors, games) that could cause a hazardous situation to arise?
Do you define risk control measures that could prevent the operation of non-specified SOUP software? (e.g. in system design, preventative measures, or labelling)
Is input from unnecessary sources prevented? (e.g. disabling floppy/CD/tape drives, modems)

Table 2. Light Weight Questions for Software Risk Management Process

What do you understand by software risk management as opposed to medical device risk management?
Do you track software risks throughout the development lifecycle?
Do you include 3rd party software anomalies as risks?
What challenges do you face in relation to this process?

The lightweight questions allows process owners' to describe the process flow and focus on the challenges and issues. These questions led the assessment process being performed as a descriptive approach rather than a prescriptive approach.

The "**Observe Objective Evidence**" activity involves a high level observation of the process artifacts rather than finding evidences for each question. The formal approach would of course include finding supporting evidence and ensuring that they are adequately recorded for presentation in regulatory audits.

The "**Identify and Report the Issues found**" activity includes analyzing the assessment session with the assessors and reporting the issues, challenges and strengths for 23 processes. The major difference of this activity from the formal assessment is that it does not include any *process attribute rating*.

4.2   Development of the Approach and Lessons Learned

The approach and the experiences that were described in this paper have evolved within the scope of a research project, the purpose of which is to adapt agile software development practices into highly regulated environments in order to achieve higher productivity levels and product quality. Four software development companies from regulated domains, based in Ireland, have been visited several times for the first phase of the project: MDevSPICE® based software process assessment for gap analysis. The profiles of these companies are given in Table 3.

Table 3. The Companies that the Approach has been implemented

Company A	Company A develops medical applications for iOS, Android, Windows 8 and Web Browser. It was formed in 2011 and since 2012, it has been developing Medical Device Software. The products that they developed are classified as Class B based on IEC 62304:2006. It's a small company including 7 people whom are developers, testers, a product manager and clinicians.
Company B	Company B develops software that is currently not safety critical but the organisation has demands placed upon them from their industry as it has to be always accurate, reliable and consistent. It includes 50 employees.

Company C	Company C develops personalized safety critical applications for patients to support them in behavior change and improve patient engagement with healthcare practitioners. It's a large scale company employing more than 150 people across three main offices in Ireland, Poland and the US.
Company D	Company D develops mobile and web applications to assist patients who are recovering from injury or operations or are dealing with chronic pain. The products that they developed are classified as Class B based on IEC 62304:2006. It is based in Ireland and 10 people work in the company.

We have started implementing the MDevSPICE® formal process assessment method in Company A, Company B and Company C. The assessment needs were specified by the sponsors and discussed with the lead assessor. The needs specified were "identify the process gaps from medical device development regulations perspective" and "understand how the gaps could be fulfilled with implementing agile practices". We commenced the assessment sessions and followed the flow in processes of the basic software development life cycle. Very detailed questions were asked to process owners, the answers were recorded and evidences observed. After 3 to 4 sessions over a two to three week time period, 1/3 of the processes still remained not assessed, but in the interests of timeliness we decided to present the partial results to Company A and Company B.

The companies were willing to proceed with the improvement phase while leaving the rest of the assessment to a later time. However the challenge with the results is that they don't represent the complete picture for the workflow. We feel that the success of the process improvement activities rely upon working on the right processes at the right time. Spending effort and resources on trivial improvements while unwittingly ignoring the ones which will have a greater effect on the quality of a process and a product would decrease the impact of the improvement initiative and the motivation for such an endeavor.

As we had already performed the formal assessments for five MDevSPICE® processes in Company C and with the lessons learned mentioned above, we have developed

the lightweight approach, and proposed it to the company sponsor and agreed upon proceeding with the new approach. It took 11 hours to complete the full assessment with 23 processes, 5 of which were assessed with the formal approach and 18 of which were assessed using the lightweight approach. If the assessment had been performed using the formal approach, it would take 37 hours as the rationale for this effort was described above. Compared to a full formal assessment approach, with 11 hours we have gained 70% from the actual time required. This would even be much more when the interruptions between the assessment sessions are considered. The major strength of this assessment is that the complete lifecycle picture of the processes and issues were assessed for the project. We then prioritized the improvement needs and defined improvement actions with relevant process owners.

Fig. 3. Evolution of the Assessment Approach based on Lessons Learned

After obtaining positive feedback from the sponsor and the process owners on implementation of the lightweight approach in Company C, we then implemented it in Company D. It took 6 hours to assess all 23 processes in Company D. We were able to schedule a back to back 2 day session with the Company, as we estimated that less time would be required for the assessment. After the assessment, we were able to point out the major issues regarding the MDevSPICE® processes in the assessed project, prioritize improvement needs and begin identifying which agile practices would be most suitable for resolving the issues specified.

Table 4. Effort Spent for Each Assessment

	Company A	Company B	Company C	Company D
# of Processes Assessed	9 processes were assessed with the formal approach	5 processes were assessed with the formal approach	5 processes were assessed with the formal approach.	23 processes were assessed with the lightweight approach

			18 processes with the light-weight approach.	
Spent Effort	12hours for the assessment	9 hours for the assessment	11 hours for assessment 8,5 hours for reporting	6 hours for assessment 3 hours for reporting

5   Conclusion

MDevSPICE® has been developed as a prescriptive process assessment and improvement framework for medical device development domain. The purpose of which is to ensure the conformance to regulatory requirements of a variety of regulatory standards whilst improving process and product quality and required safety. The formal process assessment approach of MDevSPICE® has built upon ISO/IEC 15504-Part 2. The approach includes highly detailed questions to be asked and specific evidences for base practices to be observed. This approach ensures a project's full conformance to medical regulatory requirements. However, when the major purpose of the assessment is to understand the issues in the overall lifecycle development and to proceed with the improvement actions as quickly as possible, the formal approach proves overwhelming. MDevSPICE-Adept, on the other hand proposes a detailed assessment with limited scope.

In this regard, we have developed a lightweight process assessment approach that looks across all processes at a high level rather than looking deep at a few processes with the purpose of gaining a good understanding of the overall workflow within a project or an organization. We have provided a remedy for the main shortcoming of the formal software process assessment method which is waiting too long before the assessment feedback session that leads to loss of SPI focus.

While major activities in the formal workflow remain the same such as: identification of assessment needs, selecting the processes to be assessed, establishing the assessment plan, reporting the issues and prioritization; the way we have performed these activities has significantly changed. Instead of performing the assessment over 758 questions, we now perform it over 86 questions in the light weight approach. The approach focuses upon identifying appropriate improvement opportunities rather than capability level ratings for processes. Although we no longer provide a detailed analysis for each process, the new approach provides a significant gain in terms of the time required for a full assessment and nothing is overlooked in terms of issues and challenges at the lifecycle level.

It should be noted that the light weight approach cannot be used as a readiness check before a formal regulatory audit as this requires deeper assessment of objective evidences.

To sum up, the achievements obtained with the light weight approach are:

- Specifying the issues in software development projects quicker through enabling a higher level view of the complete software development lifecycle
- Significantly reduced time to start MDevSPICE based SPI activities
- Higher motivation to proceed with the SPI activities

The future work regarding this study is to perform the approach in more regulated companies and to observe the successes achieved on SPI activities that are initiated after the light weight assessment.

Acknowledgment

References

[1]   *IEC 2006. IEC 62304: Medical Device Software - Software Life-Cycle Processes.*

[2]   *ISO 2003. ISO 13485: Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes.*

[3]   *ISO 2009. ISO 14971 - Medical Devices - Application of Risk Management to Medical Devices.*

[4]   M. Lepmets, P. Clarke, F. McCaffery, A. Finnegan, and A. Dorling, "Development of MDevSPICE®–the medical device software process assessment framework," *Journal of Software: Evolution and Process,* vol. 27, no. 8, pp. 565-572, 2015.

[5]   M. Lepmets, F. Mc Caffery, and P. Clarke, "Piloting MDevSPICE: the medical device software process assessment framework," in *Proceedings of the 2015 International Conference on Software and System Process*, 2015, pp. 9-16: ACM.

[6]   D. Stelzer and W. Mellis, "Success factors of organizational change in software process improvement," *Software Process: Improvement and Practice,* vol. 4, no. 4, pp. 227-250, 1998.

[7]   *ISO/IEC 33002:2015, Information technology -- Process assessment -- Requirements for performing process assessment*   2015.

[8]   *ISO/IEC 12207:2008 Systems and software engineering -- Software life cycle processes*, 2008.

[9]   S. T. Acuna, N. Juristo, A. M. Moreno, and A. Mon, *A Software Process Model Handbook for Incorporating People's Capabilities*. Springer Science & Business Media, 2006.

[10]   V. Basili, "The experimental paradigm in software engineering," *Experimental Software Engineering Issues: Critical Assessment and Future Directions,* pp. 1-12, 1993.

[11]   J. Lonchamp, "A structured conceptual and terminological framework for software process engineering," in *Software Process, 1993. Continuous Software Process Improvement, Second International Conference on the*, 1993, pp. 41-53: IEEE.

[12]   *Capability Maturity Model Integrated-Development*, 2010.

[13]   *ISO/IEC 15504-5:2012 Information technology -- Process assessment -- Part 5: An exemplar software life cycle process assessment model*, 2012.

[14]   F. Pettersson, M. Ivarsson, T. Gorschek, and P. Öhman, "A practitioner's guide to light weight software process assessment and improvement planning," *Journal of Systems and Software,* vol. 81, no. 6, pp. 972-995, 2008.

[15]   F. Mc Caffery, I. Richardson, and G. Coleman, "Adept–a software process appraisal method for small to medium-sized Irish software development organisations," 2006.

[16]   F. Mc Caffery and V. Casey, "Med-Adept: a lightweight assessment method for the Irish medical device software industry," 2010.

[17]   V. Casey and F. Mc Caffery, "A lightweight traceability assessment method for medical device software," *Journal of Software: Evolution and Process,* vol. 25, no. 4, pp. 363-372, 2013.

[18]   F. McCaffery, P. Clarke, and M. Lepmets, "A lightweight assessment method for medical device software processes," in *International Conference on Software Process Improvement and Capability Determination*, 2014, pp. 144-156: Springer.

[19]   K. E. Wiegers and D. C. Sturzenberger, "A modular software process mini-assessment method," *Ieee software,* vol. 17, no. 1, pp. 62-69, 2000.

[20]   M. Kauppinen, M. Vartiainen, J. Kontio, S. Kujala, and R. Sulonen, "Implementing requirements engineering processes throughout organizations: success factors and challenges," *Information and Software Technology,* vol. 46, no. 14, pp. 937-953, 2004.

[21]   A. Rainer and T. Hall, "Key success factors for implementing software process improvement: a maturity-based analysis," *Journal of Systems and Software,* vol. 62, no. 2, pp. 71-84, 2002.

[22]   M. Niazi, D. Wilson, and D. Zowghi, "Critical success factors for software process improvement implementation: an empirical study," *Software Process: Improvement and Practice,* vol. 11, no. 2, pp. 193-211, 2006.

[23]   J. Ares, R. García, N. Juristo, M. López, and A. M. Moreno, "A more rigorous and comprehensive approach to software process assessment," *Software Process: Improvement and Practice,* vol. 5, no. 1, pp. 3-30, 2000.

[24]   T. Dybå and N. B. Moe, "Rethinking the concept of software process assessment," in *European Software Process Improvement Conference (EuroSPI), Pori, Finland*, 1999.