

Medi SPICE: An Update

Fergal Mc Caffery
Regulated Software Research Group (RSRG)
Dundalk Institute of Technology (DkIT),
Dundalk,
Ireland.
Fergal.mccaffery@dkit.ie

Alec Dorling
InterSPICE Ltd.
Cambridge,
England.
alec.dorling@interspice.uk.com

Valentine Casey
RSRG
DkIT
Dundalk,
Ireland.
val.casey@dkit.ie

Abstract

This paper provides an update on the development of a software process assessment and improvement model (Medi SPICE) specifically for the medical device industry. The development of Medi SPICE was launched at the SPICE 2009 Conference. 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. Some significant amendments have been made to the Medi SPICE architecture from what was proposed at the SPICE 2009 Conference. These amendments will be presented in this paper.

1. Background

Medical device companies must produce a design history file detailing the software components and processes undertaken in the development of their medical devices. Given 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 US 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 what software activities should be performed, including risk based activities; they do not enforce any specific method for performing these activities.

2. Medi SPICE

Medi SPICE has the aim of minimizing 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.

Medi SPICE will be designed to provide 2 different types of assessments i.e. compliance and improvement. In the case of compliance assessment Medi SPICE has to cater for conformity against mandatory standards.

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 [6], and associated standards (e.g. ISO 14971[7], IEC 60601-1-4 [8], AAMI/IEC 62304 [9], TIR 32 [10] (which is now being replaced by IEC 80002-1[11]), ISO 13485 [12]) for the complete software development lifecycle.

An overall objective will be to propose a conformity assessment scheme to support first, second or third party assessment results that may be recognized by the regulatory bodies. 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 organizations 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.

3. Original plan for the development of Medi SPICE

Originally, the authors thought that the PRM and PAM of the Medi SPICE assessment standard should be derived from all 48 ISO/IEC 15504-5[13] processes and that additional practices would be added from the IEC 62304 standard. This was considered important 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.

In the original approach to Medi SPICE [14] the authors investigated the mapping between relevant ISO/IEC 15504-5 processes, the 3 safety based processes in Part 10 of ISO/IEC 15504, the eleven FDA software development areas and the 5 process area groups defined in IEC 62304.

4. Amended plan for the development of Medi SPICE

The main aim of Medi SPICE is to improve the quality of medical device software. Therefore, it is important that we carefully consider the needs of the medical device industry to ensure uptake of Medi SPICE within the medical device software industry. Hence, we set-up an advisory board containing representatives from the medical device software industry, medical device industry associations and medical device standards committees. We then invited the advisory board members to review our plans for Medi SPICE development and they highlighted that was an important issue. The medical device software industry adopts the AAMI/IEC 62304 standard for software development as it is aligned with both the regulatory needs of the FDA and the Medical Device Directive and therefore medical device organisations are familiar with the process names etc. used within the AAMI/IEC 62304 standard. Therefore, in order for Medi SPICE to be attractive to the medical device software development industry it should adopt the same structure and process names as the AAMI/IEC 62304 standard.

Therefore, the authors made a decision to change the Medi SPICE architecture to use the AAMI/IEC 62304 processes as the foundation for the model and then to incorporate practices from relevant 15504-5 processes. Additional practices will also be added from relevant medical device regulations and guidelines as required.

4.1. Medi SPICE PRM and PAM

The Medi SPICE PRM and PAM will have a process for each AAMI/IEC 62304 process. Therefore Medi SPICE will contain the following processes and sub-processes:

Software Development Process, which includes the following sub-processes:

- 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;

Risk Management Process;

Software Configuration Management Process;

Software Problem Resolution Process.

The Medi SPICE PRM will contain the following for each of the processes/sub-processes:

- process name;
- purpose;
- outcomes;
- notes.

The Medi SPICE PAM will contain the following for each of the processes/sub-processes:

- process name;
- purpose;
- outcomes;
- notes;
- the set of base practices required to accomplish the process purpose and fulfill the process outcomes;
- sample work products;
- characteristics associated with each work product;
- measurement framework and process attributes.

4.2. Medi SPICE Development

The development of Medi SPICE is currently ongoing. During the last six months the project leader focused upon developing the Medi SPICE architecture, liaising with the medical device software industry to obtain input and obtain test-bed organisations, forming an advisory board for the Medi SPICE project, obtaining resources for the project, and recently putting a project team in place that will develop Medi SPICE. The project team will deliver Medi SPICE by performing the following tasks:

1. Sequentially analyse all sentences within each of the medical device standards;
2. Categorise sentences into mandatory “Shall” statements, “Should” statements, “May” statements etc.;
3. Place all categorized sentences in a database;
4. Provide a comprehensive list of all medical device (sentences) requirements – mandatory and otherwise;
5. Group the requirements around the AAMI/IEC 62304 processes to form Medi processes;
6. Map relevant ISO/IEC 15504-5 processes against Medi processes to form the Medi SPICE PRM and PAM
 - For each Medi process:
 - Integrate this Medi process with relevant ISO/IEC 15504-5 processes:
 - Assign a process name (taken from AAMI/IEC 62304);
 - Develop a purpose;
 - Develop outcomes;
 - Develop notes;
 - Develop the set of base practices required to accomplish the process purpose and fulfill the process outcomes:
 - Base practices will be spread across multiple attribute levels;
 - Base practices will also be composed of sub-practices.
 - Develop sample work products (integrated from ISO/IEC 15504-5 and AAMI/IEC 62304);
 - Develop characteristics associated with each work product.

- Pass the developed PRM and PAM process to the advisory board for review;
- Assess feedback from the advisory board ;
- Implement appropriate changes;
- Pass the amended PRM and PAM process to the advisory board for approval.
- Develop a measurement framework and process attributes (compliant with 15504-2 [15]);
 - Develop a lightweight assessment method:
 - Trial in test-bed medical device companies;
 - Tailor based upon feedback and performance.
 - Develop a formal assessment method:
 - Trial in test-bed medical device companies;
 - Tailor based upon feedback and performance.
- 7. Rollout Medi SPICE PRM and PAM to the wider medical device industry.

5. Conclusions and Future Work

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 Software Process Improvement (SPI) path that will produce more efficient software development and safer medical devices.

6. Acknowledgements

This research is supported by the Science Foundation Ireland (SFI) Stokes Lectureship Programme, grant number 07/SK/I1299, the SFI Principal Investigator Programme, grant number 08/IN.1/I2030 and supported in part by Lero - the Irish Software Engineering Research Centre (<http://www.lero.ie>)

7. References

- [1] FDA's Mission Statement - <http://www.fda.gov/opacom/morechoices/mission.html>
- [2] CDRH, General Principles of Software Validation; Final Guidance for Industry and medical device Staff. January 11, 2002
- [3] CDRH, Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices; Guidance for Industry and medical device Staff. May 11, 2005
- [4] CDRH, Off-The-Shelf Software Use in Medical Devices; Guidance for Industry, medical device Reviewers and Compliance. Sept 9, 1999
- [5] Eagles, S. Murray, J. Medical Device Software Standards: Vision and Status, Medical Device and Diagnostic Industry, May 2001, <http://www.devicelink.com/mddi/archive/01/05/002.html>
- [6] European Council, 1993. "Council Directive 93/42/EEC Concerning Medical Devices", 14 June 1993.
- [7] ANSI/AAMI/ISO 14971, Medical devices – Application of risk management to medical devices, 2nd Edition, 2007
- [8] BS EN 60601-1-4: Medical Electrical Equipment, Part 1 - General requirements for safety. (2000)
- [9] ANSI/AAMI/IEC 62304, Medical device software – Software life cycle processes, Association for the Advancement of Medical Instrumentation, 19-Jul-2006 (replacement for SW68)
- [10] AAMI TIR32:2004, Medical device software risk management, 2005
- [11] IEC 80002-1:2009, Medical device software - Part 1: Guidance on the application of ISO 14971 to medical device software
- [12] ANSI/AAMI/ISO 13485:2003. Medical devices-Quality management systems- System requirements for regulatory purposes.
- [13] ISO/IEC 15504, Information Technology – Process Assessment – Part 5: An exemplar Process Assessment Model, ISO/IEC JTC1/SC7, International Standards Organisation, 2006.
http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=38934
- [14] F. McCaffery, A. Dorling, "Medi SPICE: An Overview", 9th International Conference on Software Process Improvement and Capability Determinations (SPICE 2009), Turku, Finland June 2009. pp. 34-41
- [15] ISO/IEC 15504, Information Technology – Process Assessment – Part 2: Performing an Assessment, ISO/IEC JTC1/SC7, International Standards Organisation, 2003.
http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=37458

