Development of the Medi SPICE PRM

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Abstract

As the importance and complexity of medical device software continues to increase there is growing demand for effective process assessment and improvement in this domain. To address this need the Medi SPICE process assessment and improvement model is being developed. Regulatory compliance is both an important and challenging aspect of medical device software development. Particularly as new regulations are being released and existing standards revised due to the attention that software is receiving within the health domain. To comply with these latest developments the Medi SPICE Process Reference Model (PRM) is being developed to conform with ISO/IEC 12207:2008 and the forthcoming release of ISO/IEC 15504-5 (currently under ballot). This paper outlines the development of the Medi SPICE PRM. It also provides details of the schedule for the full release of the Medi SPICE model.

Keywords: Medical Device Software, Software Process Improvement, SPI, ISO/IEC 15504-5:2006, SPICE. ISO/IEC12207:2008, IEC 62304:2006.

1 Introduction

Today software plays a key role in the diagnosis, treatment and care of patients in the healthcare sector. As an outcome of this the functionality, complexity and role of medical device software has increased substantially over the last few years. This is acknowledged by the European Union (EU) who in their latest amendment to the Medical Device Directive (MDD) (2007/47/EC) [1] recognizes that standalone software can now be classed as an active medical device in its own right. As a result of all these changes the complexity of developing medical device software has increased. This is coupled with the necessity to meet the regulatory requirements of the location where the medical device is to be marketed. In the United States the regulatory and approval body is the Food and Drug Administration (FDA). In the EU medical devices must comply with the MDD and receive a CE mark before they can be marketed. To achieve compliance with national regulatory requirements conformance with a number of international standards, technical reports and guidance documents are recommended by the relevant auditing bodies. In addition to the release of new regulations the revision of existing standards and the publication of new guidance documents is ongoing. These include IEC/TR 80002-1:2009 [2], ISO/IEC 12207:2008 [3], FDA guidance regarding medical device

data systems [4] FDA draft guidance in relation to mobile applications [5] and EU guidance for the qualification and classification of standalone software MEDDEV 2.1/6 [6].

Despite the regulatory bodies outlining the necessary regulations, standards and guidance documents, no specific methods for performing the required activities to achieve regulatory approval have been provided. In these circumstances medical device organizations have been compliance centric in their approach to software development and there has been very limited adoption of software process improvement within this domain. While previously this was not a vital issue due to the limited proportion of software contained in medical devices, this is no longer the case. There is now a particular requirement for highly effective and efficient software development processes to facilitate medical device software development [7]. To address this need Medi SPICE is currently being developed.

2 Medi SPICE

The objective of Medi SPICE is to provide a software process assessment and improvement model that meets the specific requirements of the medical device domain [7]. The results of a Medi SPICE assessment may be used to indicate the current state of a medical device supplier's software practices in relation to the regulatory requirements of the industry and identify areas for improvement. It may also be used by medical device software organizations to assess and improve their software development processes. Medi SPICE is being developed in line with the requirements of ISO/IEC 15504-2 [8] and contains a PRM and Process Assessment Model (PAM). It also incorporates the requirements of the relevant medical device regulations and standards. IEC 62304:2006 is a key standard for medical device software development and is based on ISO/IEC 12207:1995 [9] AMD 1[10] & AMD 2 [11], as is ISO/IEC 15504-5:2006 [12]. Both IEC 62304 and IEC 15504-5 are currently being revised and as a result of the release of ISO/IEC 12207:2008 the changes it introduced are being incorporated into these revisions. Medi SPICE is also being developed to conform with these changes.

3 The Development of the Medi SPICE PRM

The Medi SPICE PRM is currently under development. It was originally decided to base the structure of Medi SPICE on ISO/IEC 15504-5:2006 and IEC 62304:2006. Given the importance of conformance to the latest standards this approach was reviewed with the release of ISO/IEC 12207:2008. This resulted in the decision to develop the Medi SPICE PRM in line with this standard and the next release of ISO/IEC 15504-5 (currently under ballot). The structure of ISO/IEC 12207:2008 is considerably different from the previous version of the standard. This is the outcome of an extensive revision of ISO/IEC 12207:1995 AMD 1 & AMD 2 which took place in parallel with the revision of ISO/IEC 15288:2002. The focus of ISO/IEC 12207:2008 is no longer just the software engineering processes life cycle it now addresses the system engineering processes as well.

The first step in the development of the Medi SPICE PRM was the selection of relevant processes. In order to achieve this objective two key requirements needed to be consider: 1) provide effective life cycle processes and 2) facilitate conformance to the necessary medical device regulations, standards

and guidance documents. The structure of ISO/IEC 12207:2008, and the next release of ISO/IEC 15504-5 were both reviewed in detail. Analysis of the relevant medical device regulations, standards and guidance documents were also undertaken. Based on this work 42 Medi SPICE processes and 15 subprocesses were defined and released for review by interested parties from the SPICE User Group and industry experts. Following their approval the Medi SPICE PRM was structured as follows:

•The System Life Cycle Processes contains:

- 3 Agreement Processes and 7 Subprocesses;
- 6 Organizational Project - Enabling Processes and 6 Subprocesses;
- 7 Project Processes;
- 10 Technical Processes and 2 Subprocesses.

• The Software Life Cycle Processes contains:

- 6 Software Implementation Processes;
- 1 Supplementary Process and 9 Software Support Processes which includes a medical device specific process Hazard Mitigation.

Having defined the structure and processes of the PRM the developers of Medi SPICE were invited to participate in the current revision of IEC 62304. To both assist with the alignment of IEC 62304 with ISO/IEC 12207:2008 and also to provide details to the medical device community of the relationship between IEC 62304 and other medical device standards and guidelines. The decision was also taken that the next release of IEC 62304 will contain a subset of the Medi SPICE PRM.

Work then commenced on the development of the contents of the Medi SPICE PRM processes. The initial focus was on the IEC 62304 relevant processes. In line with the requirements of ISO 15504-2 each process was assigned an ID and name, with a process purpose also being defined. Based on the process purpose outcomes were identified. The purpose and outcomes addressed the requirements for an effective process and those of the medical device standards and regulations. The regulatory aspects were addressed by undertaking a detailed analysis of the standards, regulations and guidance documents with reference to each process. In addition to the normal content of a PRM the Medi SPICE PRM records the source of each outcome and where relevant an outcome is given a safety classification.

4 Current Status

The development of Medi SPICE has been warmly welcomed by the medical device industry and its release is keenly anticipated. The 14 processes which constitute the subset of the Medi SPICE PRM for inclusion in the next release of IEC 62304 have been completed. These are currently being reviewed by interested parties from the SPICE User Group, industry experts and the IEC SC62A JWG3 Standards working group (the IEC 62304 development team). It is planned that this subset of the Medi SPICE PRM will be included in the Appendix of the forthcoming release of IEC 62304. The development of the remaining Medi SPICE PRM processes is currently under way. A draft version of the Medi SPICE PRM is scheduled for released in September 2012. This will be followed by the release of the Medi SPICE PAM by the end of December 2012. The release of the complete Medi SPICE model is planned for January 2013.

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