DEVELOPING A CONFIGURATION MANAGEMENT MODEL FOR USE IN THE MEDICAL DEVICE INDUSTRY

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Abstract: This paper outlines the development of a Configuration Management model for the MEDical device software industry (CMMED). The paper details how medical device regulations associated with Configuration Management (CM) may be satisfied by adopting less than half of the practices from the CM process area of the Capability Maturity Model Integration (CMMI). It also investigates how the CMMI CM process area may be extended with additional practices that are outside the remit of the CMMI, but are required in order to satisfy medical device regulatory guidelines.

1 INTRODUCTION

Software is becoming an increasingly important aspect of medical devices and medical device regulation. Medical devices can only be marketed if compliance and approval from the appropriate regulatory bodies of the Food and Drug Administration (FDA Regulations, 2002), and the European Commission under its Medical Device Directives (European Council Directive, 1993) is achieved. Medical device companies must produce a design history file detailing the software components and processes undertaken in the development of their medical devices. Due to the safety-critical nature of medical device software it is important that a highly efficient CM process is in place within medical device companies.

CM is the discipline of *coordinating software development and controlling the change and evolution of software products and components* (Ghezzi et al, 2003). It involves the 'unique identification, controlled storage, change control, and status reporting of selected intermediate work products, product components and products during the life of a system' (Jonassen-Hass, 2002). Such CM procedures are needed to manage the vast number of elements (source code, documentation, change requests, etc) that are created and updated over the lifetime of a software system.

For many software companies, who report CM problems, CM is the first major process weakness that they are required to address. For example, as the company expands, it must fulfil the task of acquiring new customers whilst satisfying the demands of existing customers. Often these demands include product customisations which many young companies, lacking reliable revenue streams, do not feel they can ignore. In many situations this results in companies having to support multiple code bases and product versions with very limited resources. Ultimately, a detailed CM process is the only way this problem can be solved.

A study of a small Danish software firm shows how it was forced to review the number of products it developed, and the amount of work it accepted, because of CM difficulties (Baskerville and Pries-Heje, 1999). But CM is equally important in large software companies as a case study of Netscape and

Microsoft's development practices shows (Cusumano and Yoffie, 1999). Therefore, in a software company or department without CM to control product development, there is no process to assess and no basis for measurement (Fayad and Laitinen, 1997). To succeed in this area Humphrey (2000) proposes that a CM plan be developed in conjunction with the establishment of a configuration control board to manage changes to all of the baseline configuration items and to ensure that configuration control procedures are followed.

A number of 'best practice' software process improvement (SPI) models such as ISO/IEC 15504 (also known as 'SPICE') and Capability Maturity Model Integration (CMMI) have been designed to help companies manage their software development activity. For example, CMMI is an SPI improvement model which specifies recommended practices in specific process areas – including CM - that have been shown to enhance software development and maintenance capability (Chrissis et al., 1991).

This paper will investigate how thorough current medical device regulations are in relation to specifying what CM practices medical device companies should adopt when developing software. This will be achieved through comparing current medical device regulations and guidelines for CM against the formally documented software engineering 'best practices' of the CMMI for the CM process area.

2 MEDICAL DEVICE INDUSTRY

Medical device companies have to adhere to medical device regulations in relation to CM. Therefore the main area of concern for medical device companies in relation to CM is to ensure that the checklist of CM elements required by Food and Drug Administration (FDA) are in place rather than trying to improve their overall CM practices. GAMP (2001) details CM practices that medical device companies may adopt in order to comply with medical device regulations, however no documentation exists within the medical device domain in relation to how such practices could be improved by incorporating practices from formal software engineering SPI models for CM.

However, if we investigate other regulated industries such as the automotive and space industries we realise that these domains are not content with satisfying regulatory standards, but have proactively developed SPI models specifically for their domain so that they may continuously improve the development of their information

systems to achieve higher levels of safety, greater efficiency, and a faster time to market, whilst seamlessly satisfying regulatory quality requirements.

The major process improvement frameworks that currently exist, namely ISO/IEC 15504 and CMMI, do not address the regulatory requirements of either the medical device, automotive or space industries. Therefore, a new SPI model (Automotive SIG, 2005) was developed specifically for the automotive industry, this model was based upon ISO/IEC15504 (ISO, 2003) and is referred to as 'Automotive SPICE'. Likewise, a new ISO/IEC15504 based SPI model was developed specifically for the space industry, this model is known as SPiCE for SPACE (Cass and Volcker, 2000). Both of these models contain reference and assessment information in relation to how companies may improve their configuration management practices within their domain.

This paper will not address the issue of developing an entire SPI model for the medical device industry (see McCaffery et al, 2004 for full discussion), but shall instead focus upon the individual process area of CM. This work addresses an opportunity to integrate the regulatory issues and SPI mechanisms to achieve improvements that are critical to the CM of software for medical devices.

3 CMMED DEVELOPMENT

The CMMED (Configuration Management model for the MEDical device software industry) was initiated by work that one of the authors performed whilst performing research for the Centre for Software Process Technologies at the University of Ulster, Northern Ireland. This work is now progressing with Lero – the Irish Software Engineering Research Centre. The initial research work was assisted by the involvement of a steering group with a pilot of 5 medical device companies and a notified standards body (all based in Northern Ireland). Each of the five companies expressed a desire to have access to a CM model that would incorporate software process improvement practices and could fulfil the relevant medical device regulatory requirements. However, this work is now being extended to include medical device companies in the Republic of Ireland.

The CMMED may be defined as a set of activities that if performed at a base level will satisfy the CM guidelines specified in the medical device standards. However, CMMED also enables medical device companies to follow a SPI path to achieving

CMMI certification. The CMMED will be flexible in that relevant elements of the model may be adopted as required to provide the most significant benefit to the business. The model is based on the CMMI, however another model is also being developed that is based upon ISO/IEC15504. The regulations used to extend the CMMI framework will be those of the FDA and the ANSI/AAMI SW68:2001 (SW68) standard (Medical device software – Software life cycle processes).

The CMMED will provide a means of assessing the software engineering capability for the configuration management process area in relation to software embedded in medical devices (FDA/CDRH, 1997, 1999, 2005). The CMMED is being developed to promote SPI practices into the CM process adopted by medical device companies. This is an attempt to improve the effectiveness and efficiency of CM within medical device companies through investigating the mapping of medical device regulatory guidelines against the CMMI CM process area.

The mappings between the medical device standards and the CMMI specific practices for the CM process result in the CMMED being composed of a number of goals, practices and activities. The CMMED determines what parts of the CMMI CM process area are required to satisfy medical device regulations. It also investigates the possibility of extending the CMMI process areas with additional practices that are outside the remit of CMMI, but are required in order to satisfy medical device regulatory guidelines.

The following section will detail a mapping of existing software development and regulatory guidelines for the medical device industry against the CMMI for the CM process area.

4 GUIDELINE MAPPING

The FDA provides little insight into how CM should be performed other than to state that a CM plan should exist and that this should be adopted to manage configuration items for medical device software. Therefore in order to gain a greater understanding of the CM guidelines that medical device companies follow in order to achieve regulatory compliance we referred to the medical device software life cycle processes (SW68) standard. This standard was drafted for use in the medical device sector based on the lifecycle requirements of ISO/IEC 12207 (ISO, 1995). This section illustrates the CMMED structure for the CM process area. In order to achieve this, FDA

regulations & SW68 guidelines (for the rest of the paper we refer to these together as medical device standards) were mapped against the goals and practices of the CMMI CM process area.

This mapping is presented as follows: Firstly, we identify the goals that exist within the CMMI CM process area. Next the CMMI CM practices are identified within each CM goal. Then the CM activities (associated with the current practice) that have to be performed in order to comply with medical device regulations are listed. We then identify the activities that have to performed in order in to adhere to the CMMI in relation to the current practice. Finally we lists the CMMI CM activities that are required in order to meet the medical device regulatory requirements associated with the current practice. The composition of the resulting CMMED is illustrated in figure 1.
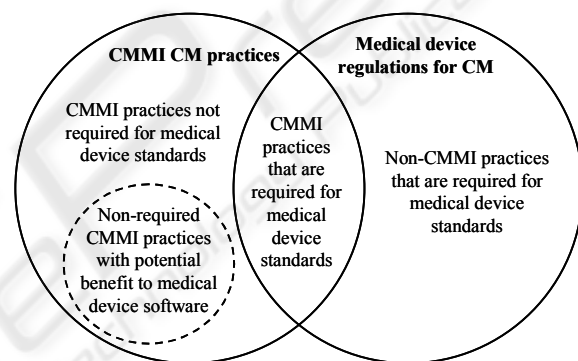

Figure 1: Composition of the CMMED.

It should be noted however, in some instances the CMMI CM activities associated with the current practice may not provide full coverage of the medical device standards and therefore these additional activities have to be added in order to achieve the full list of activities required to fulfil the objectives of CMMED.

The CMMED has three goals: Goal 1: *Establish Baselines*, Goal 2: *Track and Control Changes* and Goal 3: *Establish Integrity*. To meet each of these goals it is necessary for a number of practices and activities to be performed. Each of the following sub-sections will present the CM activities required for each of the 3 goals.

4.1 Goal 1: Establish Baselines

In order to fulfil Goal 1 *Establish Baselines* the following practices have to be performed: *Identify Configuration Items*, *Establish a CM System* and *Create or Release Baselines*.

4.1.1 Identify Configuration Items

The 4 activities that have to be performed in order to achieve regulatory compliance in relation to identifying configuration items are:
1. Select the configuration items and the work products that compose them based on documented criteria
2. Assign unique identifiers to configuration items
3. Specify when each configuration item is placed under CM
4. Identify Off the Shelf Components

The 5 activities that have to be performed in order to satisfy the CMMI practice for identifying configuration items are:
1. Select the configuration items and the work products that compose them based on documented criteria
2. Assign unique identifiers to configuration items
3. Specify the important characteristics of each configuration
4. Specify when each configuration item is placed under CM
5. Identify the owner responsible for each configuration item

The 3 activities that are common to both the CMMI and the medical device standards for identifying configuration items are:
1. Select the configuration items and the work products that compose them based on documented criteria
2. Assign unique identifiers to configuration items
3. Specify when each item is placed under CM

Therefore, in order to adhere to the medical device standards only 3 out of the 5 activities required for the CMMI in relation to identifying configuration items are necessary. However an additional activity is required in order to identify Off-the-Shelf (OTS) components as this is not included in the CMMI. Therefore 4 CMMED activities are required for identifying configuration items are:
1. Select the configuration items and the work products that compose them based on documented criteria
2. Assign unique identifiers to configuration items
3. Specify when each configuration item is placed under CM
4. Identify Off the Shelf Components. *Note: this activity is not present in the CMMI but is required in order to fulfil the requirements specified in the medical device standards.*

4.1.2 Establish a CM System

The 2 activities that have to be performed in order to achieve regulatory compliance in relation to establishing a configuration management system (CMS) are:
1. Store and retrieve configuration items in the CM system
2. Store, update, and retrieve CM records

The 8 sub-practices that have to be performed in order to satisfy the CMMI practice for establishing a CMS are:
1. Establish a mechanism to manage multiple control levels of CM
2. Store / retrieve configuration items in the CMS
3. Share and transfer configuration items between control levels within the CMS
4. Store and recover archived versions of configuration items
5. Store, update, and retrieve CM records
6. Create CM reports from the CMS
7. Preserve the contents of the CMS
8. Revise the CM structure as necessary

There are 2 activities that are common to both the CMMI and the medical device standards for establishing a CMS. Therefore, in order to adhere to the medical device standards, only 2 of the 8 activities required by the CMMI for establishing a CMS are necessary. The main differences are that CMMI requests the usage of multiple control levels of CM, as well as archiving and restoration procedures to be in place. The 2 CMMED activities for establishing a CMS are:
1. Store and retrieve configuration items in the CM system
2. Store, update, and retrieve CM records

4.1.3 Create or Release Baseline

There is only a single activity that has to be performed in order to adhere to the medical device standards in relation to creating or releasing baselines - *Document the set of configuration items that are contained in a baseline*. Whereas there are 4 activities that have to be performed in order to satisfy the CMMI practice for creating or releasing baselines:
1. Obtain authorisation from the CCB before creating or releasing baselines of configuration items
2. Create or release baselines only from configuration items in the CM system
3. Document the set of configuration items that are contained in a baseline

4. Make the current set of baselines readily available

There is only single CMMED activity that is common to both the CMMI and medical device standards for creating or releasing baselines. Therefore, in order to adhere to the medical device standards only one of the 4 activities - *Document the set of configuration items that are contained in a baseline* – is required for the associated CMMI practice is necessary.

4.1.4 Summary of CMMED Goal 1

Table 1 summarises goal 1 of CMMED (*Establish Baselines*). It may be observed from table 1 that not all of activities of the CMMI have to be performed in order to satisfy the medical device regulations (in fact only 6 of the 17 CMMI activities have to be performed). However, in order to satisfy the objectives of the CMMED 1 additional (medical device specific) activity had to be added (i.e. to satisfy goal 1 of the CMMED).

Table 1: Summary of CMMED Goal 1.

Practice	CMMI activities	CMMI activities to meet medical device standards	Additional activities to meet medical device standards
Identify CM items	5	3	1
Establish a CMS	8	2	0
Create or delete Baselines	4	1	0
Total	**17**	**6**	**1**

4.2 Goal 2: Track and Control Changes

In order to adhere to the CMMED goal 2 of tracking and controlling changes, the following specific practices have to be performed: *Track Change Requests* and *Control Configuration Items*.

4.2.1 Track Change Requests

The 5 activities that have to be performed in order to achieve regulatory compliance in relation to tracking change requests:
1. Initiate and record change requests in the change request database

2. Analyse the impact of changes and fixes proposed in the change requests.
3. Review change requests that will be addressed in the next baseline with those who will be affected by the changes and get their agreement.
4. Track the status of change requests to closure.
5. Each upgrade, bug fix, or patch for OTS software shall be evaluated, and the evaluation shall be documented

There are 4 activities that have to be performed in order to satisfy the CMMI practice for tracking change requests:
1. Initiate and record change requests in the change request database
2. Analyse the impact of changes and fixes proposed in the change requests.
3. Review change requests that will be addressed in the next baseline with those who will be affected by the changes and get their agreement.
4. Track the status of change requests to closure.

There are 4 activities that are common to both the CMMI and the medical device standards for tracking change requests:
1. Initiate and record change requests in the change request database
2. Analyse the impact of changes and fixes proposed in the change requests.
3. Review change requests that will be addressed in the next baseline with those who will be affected by the changes and get their agreement.
4. Track the status of change requests to closure.

Therefore, in order to adhere to the medical device standards all of the activities required for this CMMI practice are necessary, but not always to the same level of detail. However an additional practice is required in order to ensure that each upgrade, bug fix, or patch for OTS software is identified and evaluated, and that the evaluation is documented, as this is not included in the associated CMMI practice.
The CMMED activities for tracking change requests are:
1. Initiate and record change requests in the change request database
2. Analyse the impact of changes and fixes proposed in the change requests.
3. Review change requests that will be addressed in the next baseline with those who will be affected by the changes and get their agreement.
4. Track the status of change requests to closure.
5. Each upgrade, bug fix, or patch for OTS software shall be evaluated, and the evaluation shall be documented. *Note: this activity is not present in the CMMI but is required in order to*

fulfil the requirements specified in the medical device standards.

4.2.2 Control Configuration Items

The 4 activities that have to be performed in order to achieve regulatory compliance in relation to controlling configuration items are:
1. Control changes to configuration items throughout the life of the product
2. Obtain appropriate authorisation before changed configuration items are entered into the CM system
3. Perform reviews to ensure that changes have not caused unintended effects on the baselines
4. Record changes to configuration items and the reasons for the changes as appropriate

The 5 activities that have to be performed in order to satisfy the CMMI practice to control configuration items are:
1. Control changes to configuration items throughout the life of the product
2. Obtain appropriate authorisation before changed configuration items are entered into the CM system
3. Check in and check out configuration items from the CM system for incorporation of changes in a manner that maintains the correctness and integrity of the configuration items
4. Perform reviews to ensure that changes have not caused unintended effects on the baselines
5. Record changes to configuration items and the reasons for the changes as appropriate

As the control of configuration items is very important in terms of ensuring the integrity of medical device software it is no surprise that 4 of the 5 activities required for this CMMI practice are necessary in order to adhere to the medical device standards.

The following list shows the mapping of the medical device standards against each of the activities required by the CMMI practice for controlling configuration items:
1. Control changes to configuration items throughout the life of the product
2. Obtain appropriate authorisation before changed configuration items are entered into the CM system
3. Perform reviews to ensure that changes have not caused unintended effects on the configuration baselines
4. Record changes to configuration items and the reasons for the changes as appropriate

4.2.3 Summary of CMMED Goal 2

Table 2, summarises goal 2 of the CMMED (*Track and Control Changes*). It may be observed that almost all of the activities of this CMMI goal will have to be performed in order to satisfy the medical device standards (in fact 8 of the 9 CMMI sub-practices will have to be performed). However, in order to satisfy the objectives of CMMED 1 additional sub-practice had to be added.

Table 2: Summary of CMMED Goal 2.

Practice	CMMI activities	CMMI activities to meet medical device standards	Additional activities to meet medical device standards
Track change requests	4	4	1
Control Config items	5	4	0
Total	**9**	**8**	**1**

4.3 Goal 3: Establish Integrity

In order to fulfil CMMED goal 3: *Establish Integrity* the following specific practices have to be performed: *Establish CM Records* and *Perform Configuration Audits*.

4.3.1 Establish CM Records

The 3 activities that have to be performed in order to achieve regulatory compliance in relation to establishing CM records are:
1. Record CM actions in sufficient detail so the content and status of each configuration item is known and previous versions can be recovered
2. Identify the version of the configuration items that constitute a particular baseline.
3. Revise the status and history of the configuration item as necessary

The 6 activities that have to be performed in order to satisfy the CMMI practice for establishing CM records are:
1. Record CM actions in sufficient detail so the content and status of each configuration item is known and previous versions can be recovered
2. Ensure that relevant stakeholders have access to and knowledge of the configuration items
3. Specify the latest version of the baseline.

4. Identify the version of the configuration items that constitute a particular baseline.
5. Describe the differences between successive baselines
6. Revise the status and history of the configuration item as necessary

The process of establishing CM records is very important in terms of providing the traceability evidence that is required to meet the regulatory requirements associated with medical device software. Half of the activities (3 out of 6) required for this CMMI practice are necessary in order to adhere to the medical device standards and are therefore included in CMMED.

The CMMED activities for establishing CM records are:
1. Record CM actions in sufficient detail so the content and status of each configuration item is known and previous versions can be recovered
2. Identify the version of the configuration items that constitute a particular baseline.
3. Revise the status and history of the configuration item as necessary

4.3.2 Perform Configuration Audits

The medical device standards do not specify any activities that have to be performed in order to achieve regulatory compliance in relation to performing configuration audits. The list of the sub-activities that have to be performed in order to satisfy the CMMI practice for performing configuration audits are:
1. Assess the integrity of the baselines
2. Confirm configuration records correctly identify the configuration of the configuration items
3. Review the structure and integrity of the items in the CM system
4. Confirm the completeness and correctness of the items in the CM system
5. Confirm compliance with applicable CM standards and procedures
6. Track action items from the audit to closure

This practice in CMMI has no equivalent practice within the medical device regulations. The medical device regulations do not specify any need for auditing the CM processes and activities. Therefore CMMED contains no activities, as a result of mapping the regulatory medical device requirements for CM against each of the activities required for the CMMI practice relating to performing configuration audits.

4.3.3 Summary of CMMED Goal 3

Table 3 summaries goal 3 of the CMMED (*Establish Integrity*). It may now be determined that in order to satisfy medical device standards that not all of activities of this CMMI goal have to be performed (in fact only 3 of the 12 CMMI activities have to be performed. Additionally, no additional (medical device specific) activities have to be added in order to satisfy the objectives of CMMED.

Table 3: Summary of CMMED Goal 3.

Practice	CMMI activities	CMMI activities to meet medical device standards	Additional activities to meet medical device standards
Establish CM records	6	3	0
Perform configuration audits	6	0	0
Total	**12**	**3**	**0**

5 PRELIMINARY FEEDBACK

In order to assist with preliminary feedback, the CM process outlined by this paper has been compared against the existing practices within an Irish medical device company. A high level summary of their comments are included below.

They liked the structure of the CMMED and in particular how it enabled them to create a list of all the CM practices that they should adopt in order to adhere to the medical device standards. They also made positive comments in relation to CMMED providing additional information in relation to how their existing CM practices could be improved by incorporating guidance from the CM CMMI process area in relation how mandatory medical device activities may be performed.

Upon further consultation with the authors it has also been decided that in order to assist with SPI within the company that a process diagram shall be created, this will provide a graphical representation of the logical flow of the practices within their CM process.

6 SUMMARY AND CONCLUSION

Table 4 provides a summary of the 3 goals within CMMED. There are 40 activities required by CMMED, consisting of 38 CMMI and 2 medical device specific activities. In order to satisfy the mandatory medical device CM requirements, 19 of these activities have to be adhered to (17 CMMI and 2 medical device specific activities).

Table 4: Summary of CMMED Goals.

CMMED goal	CMMI activities	CMMI activities to meet medical device requirements	Additional activities to meet medical device requirements
Goal 1	17	6	1
Goal 2	9	8	1
Goal 3	12	3	0
Total	**38**	**17**	**2**

It is clear that following the guidelines specified in the medical device regulations will at best, only partially meet the specific goals of this CMMI process area (this would only fulfil 17 of the 38 activities required by CMMI). Since failure to perform any specific practice implies failure to meet the specific goal, with respect to CMMI, it is clear, that the goals of CM cannot be obtained by satisfying medical device regulations and guidelines during software development. But is the opposite true, *can meeting the CMMI goals for CM successfully meet FDA and SW68 guidelines?* With the exception of 2 sub-practices, performing the CMMI specific practices for CM would in general more than meet the FDA and SW68 guidelines for this area.

If a medical device company follows the CMMI guidelines for CM (with the exception of 2 activities), this will more than fulfil the CM requirements specified in the medical device regulations. However, only a fraction of the CMMI guidelines for CM will be satisfied by adhering to the medical device regulations for CM

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