A Software Process Improvement Roadmap for IEC 62304: an Expert Review

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Abstract. Manufacturers of medical devices must comply with certain legislation and regulations before they can market their products in the European Union (EU). The EU has introduced this legislation and regulation to provide the frameworks by which manufacturers can produce safe and effective medical devices in a consistent manner. The EU has accomplished this by way of Medical Device Directives and harmonised standards. Manufactures, by demonstrating compliance with a harmonised standard, can be presumed to have complied with the essential requirements of the legislation. IEC 62304 Medical device software – Software lifecycle processes is a harmonised standard. However, the standard provides no clear directions for meeting the requirements of the standard. A Software Process Improvement (SPI) Roadmap for IEC 62304:2006 has been developed as a method for aiding medical device software development organizations in implementing the standard. The Roadmap is divided into two levels, the high level consists of the Activities and Tasks necessary for the implementation of the standard, while the low level contains the Design Patterns and How-to artefacts linked to the Tasks. This paper presents the findings from the expert review of the high level roadmap.

Keywords: Software process improvement; SPI; medical device software; IEC 62304; Roadmap.

1 Introduction

To market a medical device in the European Union (EU), it must be demonstrated that it has been manufactured in compliance with a very stringent set of regulations [1]–[3]. These regulations have been introduced to achieve a consistently high level of patient and operator safety. Medical devices increasingly rely on software for their operation and increased functionality [4]. DIRECTIVE 2007/47/EC [5] clarified that standalone software can be a medical device in its own right.

Harmonised standards are European standards developed by European Standards Organisations following a request from the European Commission [6]. Manufacturers can use harmonised standards to demonstrate that their product complies with the relevant EU legislation. [7]. IEC 62304:2006 [8], is a harmonized standard that defines the life cycle requirements for medical device software [6].

The implementation of standards, such as IEC 62304, is challenging as the standard sets out the requirements that must be met but does not state how to meet them. The "*how-to*" element of standards implementation is difficult. Organisations implementing standards for the first time could engage specialist consultants to aid in the implementation. Engaging consultants can be costly and Small to Medium Sized Enterprises (SME) can find the provision of these costs prohibitive.

Roadmaps are ubiquitous in the technology domain. Since their inception in the 1970's, roadmaps have been developed for numerous other sectors. More than two thousand public-domain roadmaps, organised by topic, from over fourteen different sectors have been identified and catalogued [9].

The solution proposed here is a tailorable SPI Roadmap for the implementation of IEC 62304. The Roadmap points to a series of "*How-To*" artefacts that the organisation may utilise to direct them on how-to complete certain tasks. The completion of these tasks allows the organisation to meet the requirements of the standard associated with the particular task. The definition of the SPI Roadmap in this research, based on Flood's [10] definition with minor changes, is – "*A series of Activities, comprised of Tasks that will guide an organisation through the use of specific "How-To's" towards compliance with regulatory standards*."

The remainder of this paper is structured as follows: Section 2 outlines the related work while Section 3 outlines the proposed solution. Section 4 outlines the research method used to carry out the validation of the Roadmap. Section 5 presents the results of the expert review. Section 6 details the changes made to the Roadmap while Section 7 discusses the validity of the review. Section 8 outlines the future work to be carried out before Section 9 concludes the paper.

2 Related Work

Organisations of all sizes find difficulty in the implementation of standards. Yahya & Goh [11] reported that organisations implementing ISO 9000 encountered barriers such as: lack of understanding of the standard; constraints on resources (manpower, time, finance); lack of training and education of employees and unclear benefits of obtaining certification. As part of this research, a survey of four organisations operating in the Irish medical device software development domain was carried out to try and identify the challenges faced by organisations implementing IEC 62304. All the organisations reported that the sourcing and provision of training, incorporating traditional software development practices into an agile environment and adding new processes were among some of the challenges they faced. Additionally, the cost of implementing IEC 62304 was identified as a major challenge by 75% of the organisations surveyed. The understanding/interpretation of the requirements, sourcing template documents, production of the documentation required to demonstrate compliance, installation of a document management system, implementing overly complex processes and the rigorous planning that must be carried out at the start of the project were challenges that 25% of the respondents found difficult. Höss [12] reporting on

the experience of implementing IEC 62304 in a radiotherapy unit stated that the "*initial effort is significant and a learning curve must be overcome*", which can be costly.

One solution to overcome the challenge posed by these costs could be the use of Roadmaps. Road mapping is a process that has developed from its inception in the 1970's to an internationally accepted practice today. Bob Galvin the then CEO of Motorola is credited with the development of the first technology roadmap [13]. Roadmapping is used companywide by Motorola and they state that it is responsible for adding over two billion dollars of value to the company since the 1970's [14]. Technology roadmaps are accepted as the correct way of planning the way forward to achieve a desired goal by describing what has to be done to reach it [15]. The power of a roadmap lies in its ability to clearly show the route that is planned [16]. Cooper & Edgett reported that 38% of the best performing businesses used product development roadmaps [17]. The provision of a guide on how to implement IEC 62304 would be one method of aiding medical device software development organisations in meeting the challenges of implementing the standard.

3 Proposed Solution

The proposed solution is an SPI Roadmap, detailed in Figure 1, consisting of two levels, the high level contains the Activities and Tasks necessary for implementing IEC 62304 and the low level contains the Design Patterns and How-to artefacts that guide the organisation in how-to complete the Tasks.

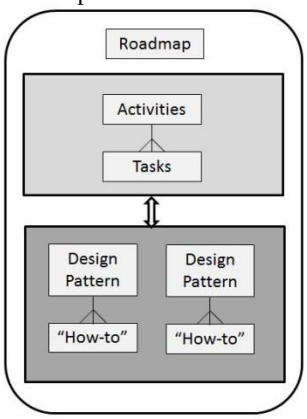

Figure 1 Roadmap Structure

The high level Roadmap comprises sixteen Activities, grouped in four bands that allow for their introduction to the organisation in a timely manner. The bands are: 1-Foundational, 2-Production, 3-Post Production and 4-Change/Problem Management. It is important to note that the Roadmap is constructed using a spreadsheet. The graphic is included in one worksheet and each Activity has its own linked worksheet containing all the associated Tasks. The graphic for the SPI Roadmap developed as part of this research is presented in Figure 2.

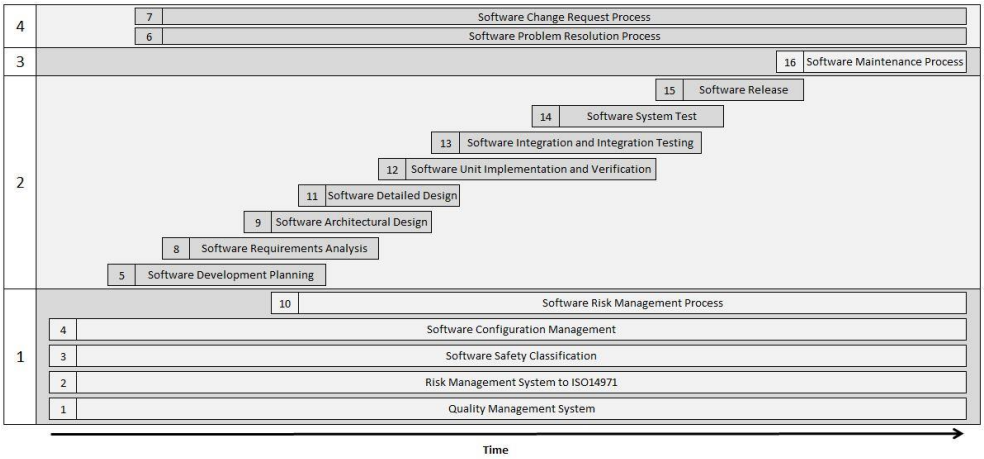

Fig. 2. Roadmap Graphic before Expert Review

The Roadmap has been developed in accordance with well-established practice [18]. The aim of the expert review was to determine if the Activities and Tasks in the high level Roadmap are correct.

4 Research Method

The research method consists of five stages as detailed in Figure 3.

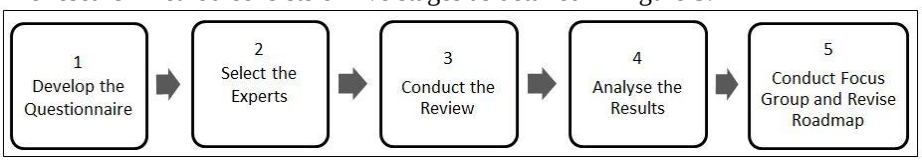

Fig. 3. Steps in Research Method

1 Develop the Questionnaire

The design of the questionnaire was developed in line with Burgess's findings [19]. Three questions were developed to determine if the high level Roadmap contains all the Activities necessary for the implementation of IEC 62304, if the order of the Activities is correct and if their grouping is appropriate. A further three questions were developed to review each of the Activities, to determine if the Tasks are suitable for the Activities, if their order within each Activity is correct and will the Tasks, once completed, fulfil the objectives of each of the Activities. A Likert scale was used in association with each of the six questions to allow the reviewer to rate the answers to the questions posed. One corresponded to "*strongly disagree*" and five with "*strongly agree*". A comment box was also included with each question to allow the expert explain their answer in more detail if they wished.

2 Select the Experts

Experts from the medical device standards community with specialized knowledge of IEC 62304 were contacted and invited to participate in the review. These same ex-

perts were also asked to nominate other experts with the same type of experience with medical device standards. Six experts agreed to participate in the review.

Expert 1 has eleven years working with the implementation of IEC 62304 and six years actively involved in developing the standard.

Expert 2 has worked for over thirty years with a major international medical device and systems manufacturer, in positions ranging from project manager, through to group manager. They have also served as a medical device software expert to the IEC and ISO joint working groups developing the standard.

Expert 3 has twenty six years' experience in medical device software, sixteen of which as an active member of the ISO/IEC working group responsible for the development of IEC 62304.

Expert 4 Commenced as a software developer for IVD devices complying with IEC 62304, progressing to project manager for similar devices. Through their own consultancy firm they advise organisations on the implementation of IEC 62304.

Expert 5 has over twenty years' experience in medical device software development and worked on the development of IEC 62304:2006.

Expert 6 has thirty five years developing hardware and software for medical devices. They are also a co-chair of the 2nd Edition of IEC 62304.

3 Conduct the Review

The experts were forwarded a copy of the spreadsheet containing the high level Roadmap together with the questionnaires. The first two Activities refer directly to other standards, the quality and risk management systems, each consisting of single tasks. For this reason the experts were not asked questions about these Tasks. Questions on whether the Roadmap included all of the Activities necessary, the order of the Activities and their grouping within the Roadmap constituted the first questionnaire. Their answers were recorded on a five level Likert scale. The experts could add additional explanation of their answers or comments in the box provided. The second questionnaire included questions on the Tasks contained in each Activity: are they suitable for the Activity, are they in an appropriate order and are they complete. A comment box as described above was also included.

4 Analyse the Results

Two methods are utilized to analyse the results. Firstly the mean and standard deviation are calculated for the answers to each question and secondly the comments made were manually analysed using a content analysis approach.

5 Conduct Focus Group and Revise Roadmap

Following the analysis, a focus group consisting of three experts with experience of medical device software development, roadmaps and software process improvement from the Regulated Software Research Centre based in Dundalk Institute of Technology, Ireland, was convened to consider the results of the expert review. The sessions were arranged as described by Tremblay et al [20]. The results of the Likert scale answers and the expert's comments were tabulated along with the Activities and Tasks that they referenced. The focus group discussed each comment and a consensus was reached as to whether or not a change was required.

5 Results

5.1 The Roadmap

The mean and standard deviation (SD) were calculated for the results recorded for each question. It was found that all of the Activities that are necessary (mean 4.6, SD 0.5) for the implementation of IEC 62304 are included and that the grouping of the Activities (mean 4.0, SD 1.1) is appropriate. There is no strong feeling as to whether the order of the Activities (mean 3.0, SD 0.6) is correct.

The content analysis of the comments on the Roadmap resulted in the creation of four categories:

1. **Structural**: Comments concerned with the graphical representation of the Roadmap.
2. **Regrouping of Activities**: Comments with regard to the placement of the Activities within the individual bands comprising the Roadmap.
3. **Timing of Activities**: Comments about the timeline by which the Activities are introduced to the organisation.
4. **Definition of Terms used in Roadmap**: Comments referencing certain terms used in the Roadmap and where confusion might occur due to their use in the context of a medical device software improvement roadmap.

Structural: This category attracted two comments. The main concern was that the graphical representation of the roadmap implied that agile methods were not an option. To address this issue, more emphasis is being placed on the fact that the Roadmap is not a program but rather a timeline by which the Activities are introduced to the organisation. The objective of the Roadmap is to aid the implementation of the standard. It is important to note that similar to IEC 62304, the Roadmap does not prescribe any particular life cycle model. The focus group concluded that the "bars" in band 2, the production block, should be widened to emphasize that agile methods are not proscribed.

Regrouping of Activities: Two comments were made under this category. The first, that Software Risk Management is part of Software Safety Classification, was considered by the focus group, but it concluded that these activities should remain as individual Activities but that Software Risk Management should be introduced earlier in the timeline. The Activity will be moved to the left, before activity 6 and 7. The second comment, that Software Configuration Management should be placed in band 4 along with the Software Problem Resolution and the Software Change Request Activities, was considered by the focus group but was found that while there was a link between the activities, Software Configuration Management should stay in band 1.

Timing of the Activities: Four comments were made on the timing of the Activities e.g. "*All band 2 Activities should start before any one of them is complete.*" The comments will be addressed by including a new worksheet titled "*About*". This worksheet will explain the graphic in more detail and how it should be interpreted. It will

explain that the Roadmap is not a programme but rather a timeline for the introduction of the Activities to the organisation implementing IEC 62304.

Definition of Terms used in Roadmap: A total of three comments were made on the meaning of certain words used in the Roadmap, for example, the meaning of "*release*" in the roadmap was questioned. The term has a specific meaning when used in agile software development, while the term when used in the Roadmap has a different meaning. A worksheet will be inserted in the Roadmap, titled "*Definitions*" and will include definitions for the terms used in the Roadmap where concerns were raised. The terms will be capitalized in the text of the Roadmap to indicate, similar to the use of capitalization in the standard, that there is a definition for the word included in the definitions worksheet. Also, Activity fifteen will be renamed "*Software Release at a System Level*" to avoid confusion.

5.2 The Activities

Questions 4, 5 and 6 related to each Activity. The mean and standard deviation were calculated for the results recorded for each question and are presented in Table 1.

Table 1 Results of the Questionnaire on the Activities – Anomalies highlighted

		Question 4		Question 5		Question 6	
Activity	Activity Title	Mean	SD	Mean	SD	Mean	SD
3	Software Safety Classification	4	1	5	0	4.5	0.5
4	Software Configuration Management	3	0	4	0	2	0
5	Software Development Planning	3	0	4	0	5	0
6	Software Problem Resolution Process	4	0	1	0	4	0
7	Software Change Request Process	4	0	2	0	2	0
8	Software Requirements Analysis	3	0	3	0	3	0
9	Software Architectural Design	4	1	4	1	4.5	0.5
10	Software Risk Management Process	3	0	3	0	4	0
11	Software Detailed Design	4	1	5	0	4	0
12	Software Unit Implementation and Verification	4	1	4	0	4	0
13	Software Integration and Integration Testing	3	0	3	1	4	1
14	Software System Testing	3	1	2.5	0.5	3	1
15	Software Release	1	0	4	0	3	0
16	Software Maintenance Process	3	0	5	0	5	0

Question 4 - Tasks are suitable for the Activity: There is an overall consensus that the Tasks are suitable for each of the activities. However, Activity 15 - Software Release - was most problematic returning a mean of 1.0 and SD 0.

Question 5 - The order of the Tasks within the Activity is correct: There is a consensus with eleven of the Activities. However, Activities 6 (mean 1.0, SD 0), 7 (mean 2.0, SD 0) and 14 (mean 2.5, SD 0.5), are the subject of some disagreement on the order of the Tasks.

Question 6 - The Tasks once completed will fulfil the objective of the Activity: Two of the Activities 4 and 7 scored a mean value of 2.0, SD 0.0, while the remainder of the Activities achieved scores of 3.0 and above indicating that the experts agreed that the Tasks once completed will fulfil the objective of the Activity.

Forty five comments were returned with regard to the Tasks and these were categorized under seven headings, presented in Table 2.

Table 2 Categorization of Activity Comments

Category	Title	Number of Comments
1	Coverage of Activity	5
2	Order of Tasks (Timing)	11
3	Coverage of Task	11
4	Wording of Task	6
5	Amount Detail (Intent)	7
6	Definitions	2
7	Changes to IEC 62304 in 2nd Ed	3
Total		45

Coverage of the Activity: Of the five comments made, the main concern was in regard to Activity 6 – Problem Resolution Process in that there was no reference to reproduction of the problem in any of the Tasks. This concern will be addressed by including a reference to reproducibility in the Task and in the associated Design Pattern and "*How-to*" artefact.

Order of the Tasks (Timing): Eleven comments over seven Activities were recorded. Each comment was considered by the focus group and the order of the Tasks within three of the Activities was altered. An example being Activity 7 Software Change Request Process – where the comment regarding the order of Tasks 7.6 – verify changes and 7.7 – retest after changes is acknowledged and they will be reversed in the final Roadmap, verification being executed after all changes and testing has being made.

Coverage of the Task: Eleven comments were made regarding eight Tasks in seven of the Activities in this category. An example concerns Activity 4 - Software Configuration Management which comprises four Tasks. Task 4.1 is concerned with the establishment of the configuration scheme and 4.2 with the documentation of the scheme including any SOUP items being used. The reviewer was concerned that the Task did not identify all the elements that are used in the creation of the software, e.g. environment, tools, release manual etc. The focus group agreed that a non-exhaustive list of elements should be included in Task 4.1 and that SOUP should be referenced directly in Task 4.2 and because SOUP includes open source software which may be updated or upgraded by anybody, a note to this effect will be included in the Task.

Wording of the Task: In this category six comments were made regarding four of the Activities. For example Activity 13 - Software Integration and Integration Testing attracted a comment with regard to the use of the word "*ensure*" in Task 13.6 – *"Ensure that the integration test record contents include:".* The standard uses the word "*shall*". The focus group concluded that the word ensure should be removed and either "*shall*" or "*must*" used in its place. The task will be reworded to include the word "*ensure*".

Amount of Detail contained in the Task: Comments were made with regard to seven Tasks. As an example Activity 16 Software Maintenance Process comprises six Tasks and the comment was in relation to Tasks 16.4, 16.5 and 16.6 and their references to other Activities in the Roadmap. The reviewer was concerned that the tasks were duplications and this might lead to issues with the practical implementation of a Quality Management System. Following a discussion on the matter the focus group

concluded that the Tasks should be maintained to preserve the completeness of the mapping of the requirements to the Roadmap, but that the comment should be addressed by cross referencing the other Activities.

Definition of Certain Terms: Comments were made with regard to the use of each of the words, "*documented*" in Activity 5 and "*ensure*" in Activity 13. The focus group agreed that a definition for "*documented*" should be included in the Roadmap and Task 13.6 will be reworded using the word "*shall*".

Changes to IEC 62304 in the 2nd Edition: Comments were made in relation to each of three changes being made in the 2nd edition of IEC 62304. For example the section on Software Safety Classification in the 2015 version of IEC 62304 has been practically rewritten, however, it does not materially change any of the Tasks in the Activity and the focus group decided that no changes were deemed necessary.

6 Revision of the Roadmap

Following the focus group all the agreed changes were made to the Roadmap and the revised graphic is presented in Figure 4.

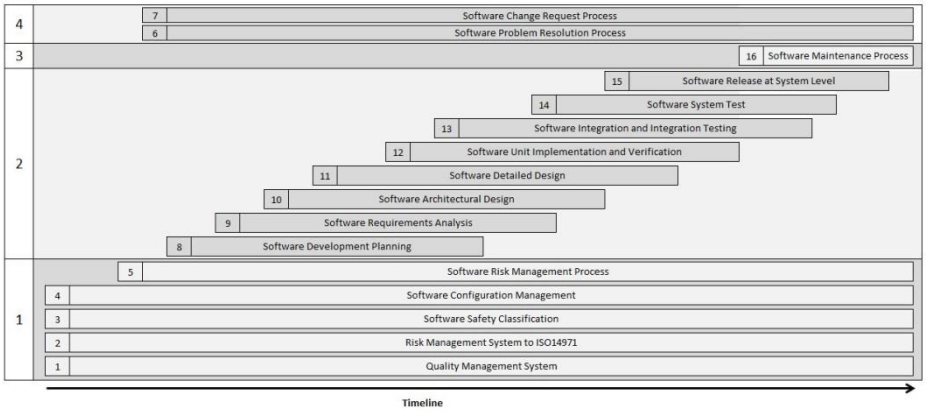

Fig. 4. Final Roadmap Graphic

The first point to note is that the four bands have been maintained as in the original Roadmap. The Software Risk Management Process, Software Problem Resolution and Software Change Request Activities have all been moved to the left so that they are introduced before Software Development Planning which now becomes Activity 8. The Activities in band 2 – the production activities – are all widened to help negate the impression that agile development is not an option. Activity 15 is renamed Software Release at System Level so that there is no confusion with the use of the term "*release*" by the development team. The remaining changes are as follows:

- A worksheet titled "*About*" has been added to explain exactly what the aim of the Roadmap is.

- A worksheet titled "*Definitions*" has been added and includes all the definitions that are used in the Roadmap.
- Words that are defined for the Roadmap are capitalised within the text of the Tasks.
- A note has been included in Task 4.1 regarding SOUP.
- A note has been added to Task 6.1 regarding reproducibility
- A note has been included in Task 6.2 referencing Task 6.8.
- The order of Tasks 7.6 and 7.7 have been reversed.
- A note has been added to Task 9.2 with regard to hardware failures.
- The order of Tasks 13.5 and 13.6 have been reversed.
- The order of Tasks 14.1 and 14.2 have been reversed.
- Task 13.5 has been reworded.
- Task 16.4, will include a reference to Activity 6, and Tasks 16.5 and 16.6 will include references to Activity 15.

7 Validity

The fourteen Activities were divided into four sub sections, each containing either three or four Activities. Each of the experts was requested to review one sub section. The result was that eight Activities were reviewed only once while the remaining six received two reviews. Five of the experts have participated in the development of the standard, while the remaining expert has fifteen years' experience in its implementation. Because of their expertise the threat to validity is considered minimal.

8 Future Work

The next phase of the validation process is industry trial, where two organisations engaged in medical device software development have been recruited to trial the roadmap. The organisations will be assessed before the implementation of the Roadmap using a tailored MDevSpice® assessment. Following the implementation of the Roadmap the organisations will be reassessed using the same assessment tool and the results analysed. Interviews will be conducted with the participant organisations to determine the usefulness and ease of use of the Roadmap within the organisation.

9 Conclusions

Medical devices increasingly rely on software for their operation and increasing functionality. Marketing of a medical device within the EU is dependent on it meeting very stringent regulations. Demonstrating compliance with these regulations can be achieved by developing the medical device in accordance with harmonized standards. Medical devices increasingly rely on software for their operation and control. The standard for medical device software life cycles, IEC 62304:2006 is a harmonized standard. However, the standard tells you what to do but not how to do it. This is a

major challenge for small medical device software development organisations. The Roadmap, a guide to regulatory compliance, developed under this research is a possible solution to this problem.

Six experts reviewed the Roadmap and the Activities. The results indicated that the Roadmap did include all the Activities necessary for implementing IEC 62304 and that their grouping into the four bands is appropriate. The results also indicated that the Tasks are suitable for each Activity and that once completed will fulfil the objective of the particular Activity. A total of forty five comments were made suggesting changes to the Tasks and Activities. A focus group reviewed the results and comments and agreed that a total of sixteen changes should be made. The changes have been implemented and the Roadmap will now be piloted within two medical device software development organisations.

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