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Methods of Extracting and Providing R&D Documentation Guideline for Licensing Medical Device Software

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ABSTRACT

The safety and performance of medical device software is managed through life-cycle processes, which represent the entire process of research and development (R&D). The life-cycle process of medical device software is represented by an international standard called IEC 62304, ISO/IEC 12207. In order to license the product, the manufacturer must have document artifacts that comply with the IEC 62304 standard. However, these standards only describe the content of the activity and do not provide a method or procedure for documentation. Therefore, this paper suggests R&D documentation guidelines that assist medical device software developers to have R&D documents conforming to the standards. For this purpose, this study identifies the requirements related to documentation among the requirements existing in the standard and extracts them in the form of guidelines showing only the core information of the requirements. In addition, through the Web framework implemented based on this research, the developer can evaluate whether the technical documents are written in accordance with the R&D document guidelines. Medical device software manufacturers can efficiently produce high-quality research and development documents through R&D documentation guidelines, and they can have standards-compliantresearch and development documentation required for licensing procedures.

☞ keyword : Medical Device Software, Standard, IEC 62304, ISO/IEC 12207, Documentation Guideline

1. Introduction

Medical device software must be more tightly controlled in safety and performance than software in other areas. For this, Korea and many countries in Europe have made sure that the research and development(R&D)of the product has been properly performed during the licensing of medical device software, and have enacted the international standard of IEC 62304 as a guideline for R&D. Therefore, medical device software manufacturers comply with standards related to medical device software including IEC 62304, and they are licensed through documents artifacts [1]. IEC 62304 is a standard for the medical device software life-cycle process [2]. It ensures the safety and performance of medical device software through verification of software artifacts and validation of all software life cycle. In other words, this standard requires not only a testing-based activity represented by the V&V(Verification & Validation) model, but also all R&D procedures which are performed correctly. In addition, ISO / IEC 12207 international standard is a standard that developers refer to for research and development of medical device software. ISO / IEC 12207 is the standard for presenting life-cycle processes for general software [3], which is the basis of the contents of IEC 62304.

However, these international standards only abstractly describe the activity of the process, but do not specifically describe the methodor procedure for R&D documentation. That is, the developer knows the requirements of the life-cycle process from the standard, but does not provide the scope or method of the document artifacts that must be created for licensing. In addition, research on software engineering methodologies such as testing and configuration management required to fulfill the requirements of the standard is active [4, 5], and there is little research on

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documenting them. Therefore, manufacturers have difficulty in preparing R&D documents that meet the standard requirements. In addition, the evaluation of the written R&D documents depends on the domain experts, and there is a need for a method for manufacturers to perform qualitative evaluation of R&D documents themselves [6, 7].

This paper extracts the specification that requires documentation among the contents of the standard with the concept of 'R&D Documentation Guideline', and enables medical device software stakeholders to write and evaluate R&D documents that comply directly with the standards. Chapter 3 merges the configurations of IEC 62304 and ISO/IEC 12207 and defines the documentation guidelines from the documentation requirements. Chapter 4 proposes a method for providing the defined R&D documentation guidelines, then we confirm the possibility of the proposed method by confirming that the developer has written and evaluated the record document through the guidelines. Following the documentation guidelines, developers can have technical documents that complies with all standards, and they can efficiently prepare the licensing procedures of medical device software.

2. Related Work

There is an ISO/IEC 15504 standard called 'Software Process Performance Evaluation Framework (SPICE)' for evaluating software R & D [8]. (MDevSPICE), which specializes in medical device software [9]. These studies assess the level of research and development processes by comparing requirements specifications and software artifacts based on ISO/IEC 12207 and IEC 62304 standards. However, it evaluates only the list of products such as codes and documents, but does not evaluate the contents of research and development documents qualitatively.

In addition, there is a study on the Standard Conformity Framework (SCF) that enables research and development records to be written in conformity with standards [10,11]. These studies provide a proper template for document artifacts, allowing developer to create documents that conform to standards. However, because it is not a framework defined based on standards in the software field, there is a limitation that software life-cycle process requirements can not be covered.

Therefore, this paper suggests R&D documentation guidelines to overcome the limitation that the standard based R & D document can not be written through the previous studies. The requirements for documentation in the requirements of the standard are extracted as a guideline of the type presented in this study to enable the qualitative assessment of whether the document meets the requirements of the standard as well as the R & D document .

3. Method for Extracting R&D Documentation Guideline

The IEC 62304 standard specifies five processes (development, risk management, configuration management, defect management, maintenance) in the medical device software life cycle from Chapters 5 to 9. ISO/IEC 12207 defines the life cycle process for general software R&D in chapters 6 to 7. They present the contents of software research and development, and they are composed of 'Process-Activity-Task' levels. Task means 'requirements' which is the minimum unit. This chapter identifies only the items with the guidance of documentation among the standard requirements and extracts them in the form of documentation guidelines that provide only the core information.

3.1 Standard based R&D Specification

The framework proposed in this study allows medical device software developers to comply with two international standards (IEC 62304, ISO/IEC 12207). IEC 62304 is a standard established to reflect the characteristics of medical device software, and ISO/IEC 12207 is a standard for general purpose software that presents more abstract and comprehensive R&D requirements. This study presents the contents of a new R&D process reflecting the characteristics of these two standards. The list of Table 1 is the processes that merged the table of contents of IEC 62304 based on the contents of ISO/IEC 12207. Then the framework developed by this study presents the R&D specification of the two standards to the developer as shown in this table.

(Table 1) Contents of ISO/IEC 12207 and IEC 62304

Contents		
6. Medical Device Software - Research Process		
6,1 Agreement Processes		
	Acquisition Process	
	Supply Process	
6.2 Organizational Project-Enabling Processes		
	Life Cycle Model Management Process	
	Infrastructure Management Process	
	Project Portfolio Management Process	
	Human Resource Management Process	
	Quality Management Process	
6.3 Project Processes		
	Project Planning Process	
	Project Assessment and Control Process	
	Decision Management Process	
	Risk Management Process	*
	Configuration Management Process	*
	Information Management Process	
	Measurement Process	
6.4 Technical Processes		
	Stakeholder Requirements Definition Process	
	System Requirements Analysis Process	*
	System Architectural Design Process	*
	Implementation Process	
	System Integration Process	
	System Qualification Testing Process	
	Software Installation Process	
	Software Acceptance Support Process	
	Software Operation Process	
	Software Maintenance Process	
	Software Disposal Process	
7. Medical Device Software - Development Process		
7.1 Software Implementation Processes		
	Software Implementation Process	*
	Software Requirements Analysis Process	*
	Software Architectural Design Process	*
	Software Detailed Design Process	*
	Software Construction Process	
	Software Integration Process.	*
	Software Qualification Testing Process	
7.2 Software Support Processes		
	Software Documentation Management Process	
	Software Configuration Management Process	*
	Software Quality Assurance Process	
	Software Verification Process	*
	Software Validation Process	*
	Software Review Process	
	Software Audit Process	
	Software Problem Resolution Process	*
	Software Reuse Processes	
* : Indicates where IEC 62304 processes are merged from the table of contents in ISO/IEC 12207		

3.2 Documentation Requirement

IEC 62304 and ISO/IEC 12207 have 215 and 620 requirements, respectively, of which there are requirements to be specifically documented. In order to define the documentation guidelines, we extract requirements that contain the contents for recording activity result. This is done on the basis of the use of the words "document" or "make record" in the content of the requirement.In addition, 'M(Mandatory) / O(Optional)' attributes are given depending on whether the documentation requirements should be performed unconditionally. This is distinguished by whether the requirement has the word "shall" or "should". Table 2 shows the configuration for the documentation requirements extracted from the standard, which indicates that the manufacturer must perform documentation by a total of 124mandatory requirements. The following examples are the requirements of the two standards with thecharacteristics of the documentation requirements.

ex1) ISO / IEC 12207-6.4.1.3.5.1 The project shall record the stakeholder requirement.

ex2) IEC 62304-5.2.6 The MANUFACTURER shall verify and document that the software requirements:

(Table 2) Configurations of Documentation Requirements for Standards

Category	DR(M)	DR(O)
6. Research Process		
ISO/IEC 12207	33	6
IEC 62304	16	3
7. Development Process		
ISO/IEC 12207	40	2
IEC 62304	35	7
Total	124	18
DR: Documentation Requirement M/O: Mandatory/Optional		

3.3 Documentation Guideline

Documentation guidelines are descriptive texts that enable users to easily create and evaluate R&D documents through core information of the documentation requirements. The documentation guidelines are structured to providea variety

of information on the requirements, as shown in Figure 1. Especially, the requirement has a 'document keyword' information, which allows the user to create or evaluate a document based on whether or not the document content includes keywords.

In (source of documentation guideline) ,
Require you to (mandatorily / optionally) create the (target document) including the (document keyword)

(a) Construction of Documentation Guideline

In IEC 62304 - 5.2.1 ,
Require you to mandatorily create the 'SRS' including the "System of medical device, System requirement"

(b) Example of Documentation Guideline

(Figure 1) Format and Example of Documentation Guideline

Figure 1 (a), the documentation guidelines have a total of four main information items.

-source of documentation guideline

: Indicates the source for the developer to see the contents of the standard directly if they want to read the detailed description.

- mandatorily / optionally

: Indicates whether the developer should document the contents of the guideline, and is used as important information to prepare for licensing of the product.

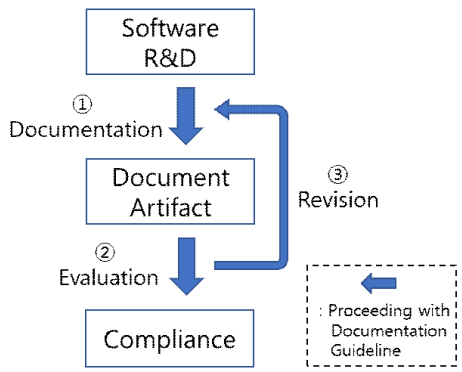
- target document

: Indicates the title of the document so that it can record research and development activities in the appropriate document from the list of documents the manufacturer has.

- document keyword

: The developer will recommend keywords that should be included in the document so that they can write documents that meet the standard requirements after the R&D activities. In addition to providing information on document preparation, this item is used as a basis for document evaluation described below.

Figure 2 shows the flow diagram for usage of documentation guideline. The user follows the instructions of the documentation guidelines during the R&D. For example, in the case of Figure 1 (b), the developer must record R&D activities in the SRS, including the keyword 'System of medical device, System requirement'. Subsequently, the R&D documents are evaluated as to whether or not keywords are included in the content, and if not, the contents are revised to include all the keywords. This means that the evaluation of the document through the keyword can guarantee the conformity to the standard.



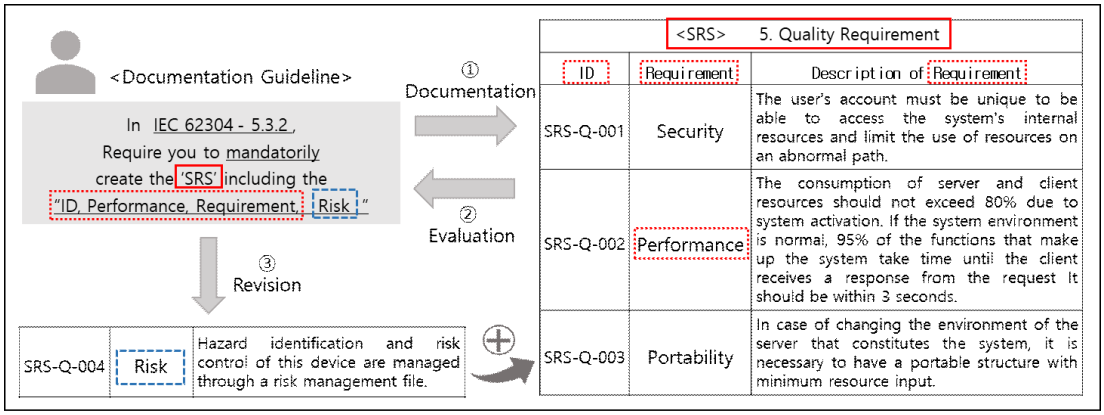
(Figure 2) Flow Diagram for using Documentation Guideline

4. Methods for Providing R&D Documentation Guideline

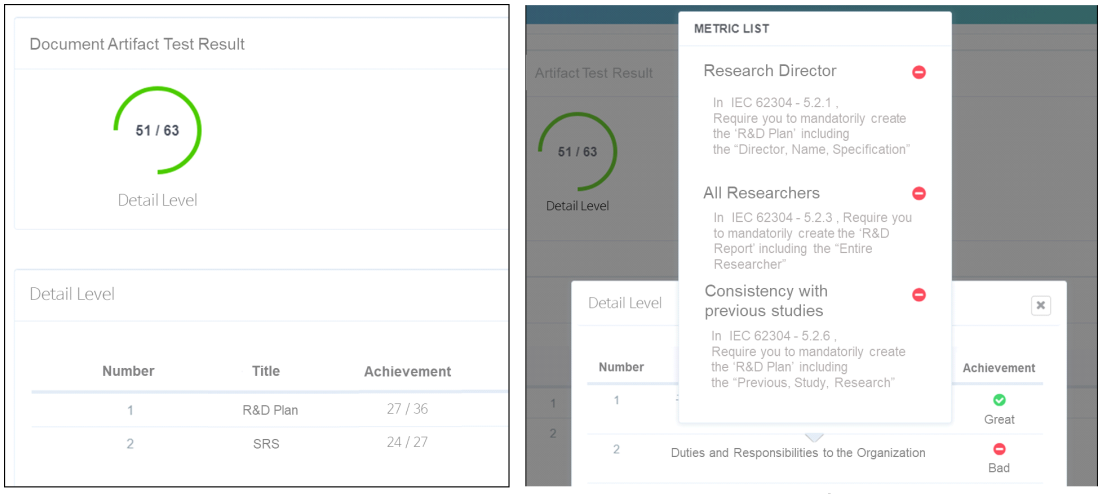
Through documentation guidelines, users can create and evaluate medical software R&D document that complies with the documentation requirements specified by IEC 62304. Figure 3 shows the scenarios according to the flow chart, details of whichare as follows:

① Documentation: During the research and development of medical device software, users can generate documents and compose a list of documents that conform to the standards without having to directly analyze the contents of the standards through the documentation guidelines.

② Evaluation: Documentation guidelines are evaluated by examining whether the document indicated by the keyword contains all of the keywords. This can be



(Figure 3) Scenario for applying Documentation Guideline



(Figure 4) Web-based R&D Documentation Guidelines Framework

automated based on searching macro or similarity evaluations of the document content.

③ Revision: Evaluation result of document. Figure 4 shows that the keyword 'RISK' is missing from the keyword 'ID, Performance, Requirement, Risk' in 'SRS'. The guideline has the attribute 'Mnadatorily', so the developer must document all keywords. Therefore, the developer should understand the details of the requirements through the standard source information, conduct research and development on 'RISK', and revise the document to include the keyword 'RISK'.

The process of ① through ③ is repeated until all research and development documents meet the documentation guidelines, which enables manufacturers to efficiently provide high quality research and development documents.

Figure 4 is an example of a web-based framework provided to the user according to the scenario of Figure 3.The developer will proceed with the R&D in the order of the process composition table of the two standards in Table 1, and the contents of the requirements to be documented in each list can be provided through the documentation

guidelines. Once all the R&D documents have been written, the developer can perform document evaluation by checking that the document contains the keywords required by the documentation guidelines, and the resulting output is shown in Figure 4(a). The framework indicates how much documentation guidelines have been achieved for each document, which is the degree of conformity of the R&D document.

In this example, the developer creates documents named 'R&D Plan' and 'SRS' into the documentation guideline evaluation framework. The evaluation framework checks whether all the keywords required by the standard are included in the 'R&D Plan' document and checks whether all the keywords required by the standard are included in the 'SRS' document. In the IEC62304 standard, there are a total of 36 documentation guidelines for the 'R&D Plan' and 27 documentation guidelines for 'SRS', which figure that we have satisfied the documentation specifications for 27 and 24 of these.

In addition, the developer can revise the document through the evaluation result. The framework shows the documentation guidelines that the user did not grasp and did not satisfy as shown in Fig. 4 (b). Developers will be able to modify their R&D documents to meet the standard requirements through the key information provided by the R&D documentation guidelines. The evaluation-revision process is repeated until all the documentation guidelines are satisfied.

5. Conclusion and Further Research Issues

This paper defines the documentation guidelines by extracting the core information of the requirements for documentation so that the research and development documents can be produced according to the requirements of the two international standards, IEC 62304 and ISO/IEC 12207. The documentation guidelines assist in the creation and evaluation of R&D documents through corekeywords of the requirements. This allows medical device software manufacturers to construct standards-compliant research and development documents and to have high-quality research and development documentation to ensure the quality of medical device software and to provide the necessary records for licensing procedures.

Future research will include research on extracting R&D documentation guidelines from standard requirements by applying text mining techniques. By automating the methodology presented in this study, we canautomatically extract the R&D documentation guidelines when the user enters the standard. And we will improve the method of evaluating the written R&D documents.

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