Software as Medical Device
Issue and Trend in Korea

2015.11

MINISTRY OF
FOOD AND DRUG SAFETY

Software as Medical device ?

Scope

○ Medical Device Act, Article 2 – The term “medical device” in this Act means an instrument, machine, device, material, or any other similar product specified in the subparagraphs as one used, alone or in combination, for human beings or animals.

1. A product used for the purpose of diagnosing, curing, alleviating, treating, or preventing a disease
2. A product used for the purpose of diagnosing, curing, alleviating, or correcting an injury or impairment
3. A product used for the purpose of testing, replacing, or transforming a structure or function
4. A product used for birth control

○ Applies to stand-alone software(Picture archiving and communication system software), Embedded software(ultrasound imaging system), mobile medical application

Software as Medical device ?

○ Medical device Software

Means stand-alone software, Embedded software, mobile medical application as software system intended for use as medical device

* Stand-alone software : Medical device software as operating at same environment of general-purpose computer, and itself has accord with intended use of medical device
* Embedded software : software that is operated and embedded in medical device system



Software as Medical device ?

Medical Mobile App

○ Apps that remotely control a medical device

○ Apps that display, store, analyze the data from a connected medical device(alarm, etc.)

☞ Apps are excluded that simply targeted to in their own health management

○ Apps that use the mobile platform by using attached or added sensors, electrodes, etc.

○ Apps that use the mobile platform by using built-in sensor

(ex : The measurement of blood oxygen saturation using the light source of smart phone)

○ Apps that perform patient-specific analysis and provide patient-specific diagnosis, or treatment recommendations

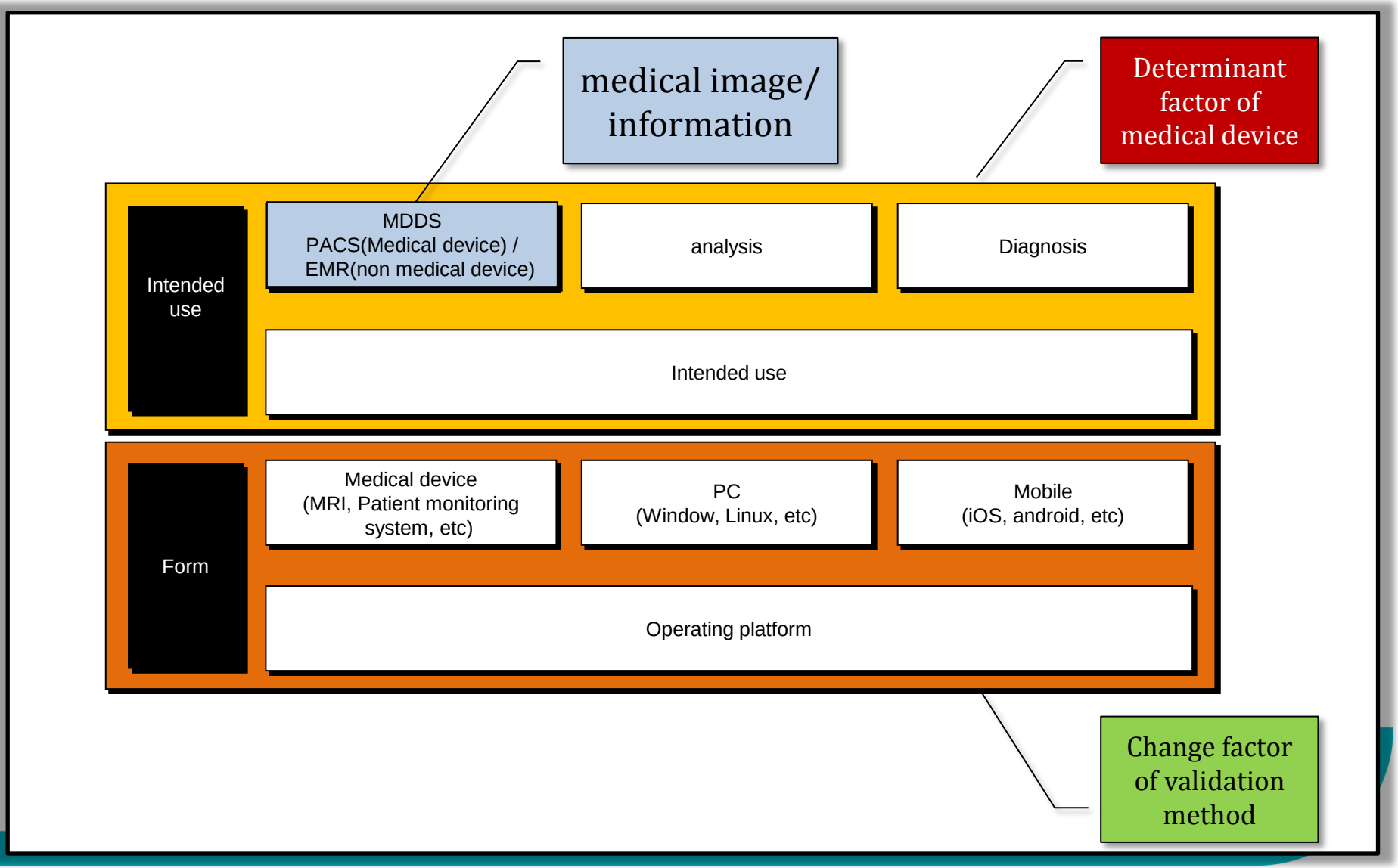
Non Mobile Medical App

○ Apps that provide general health information(emergency care information, anatomy diagrams)

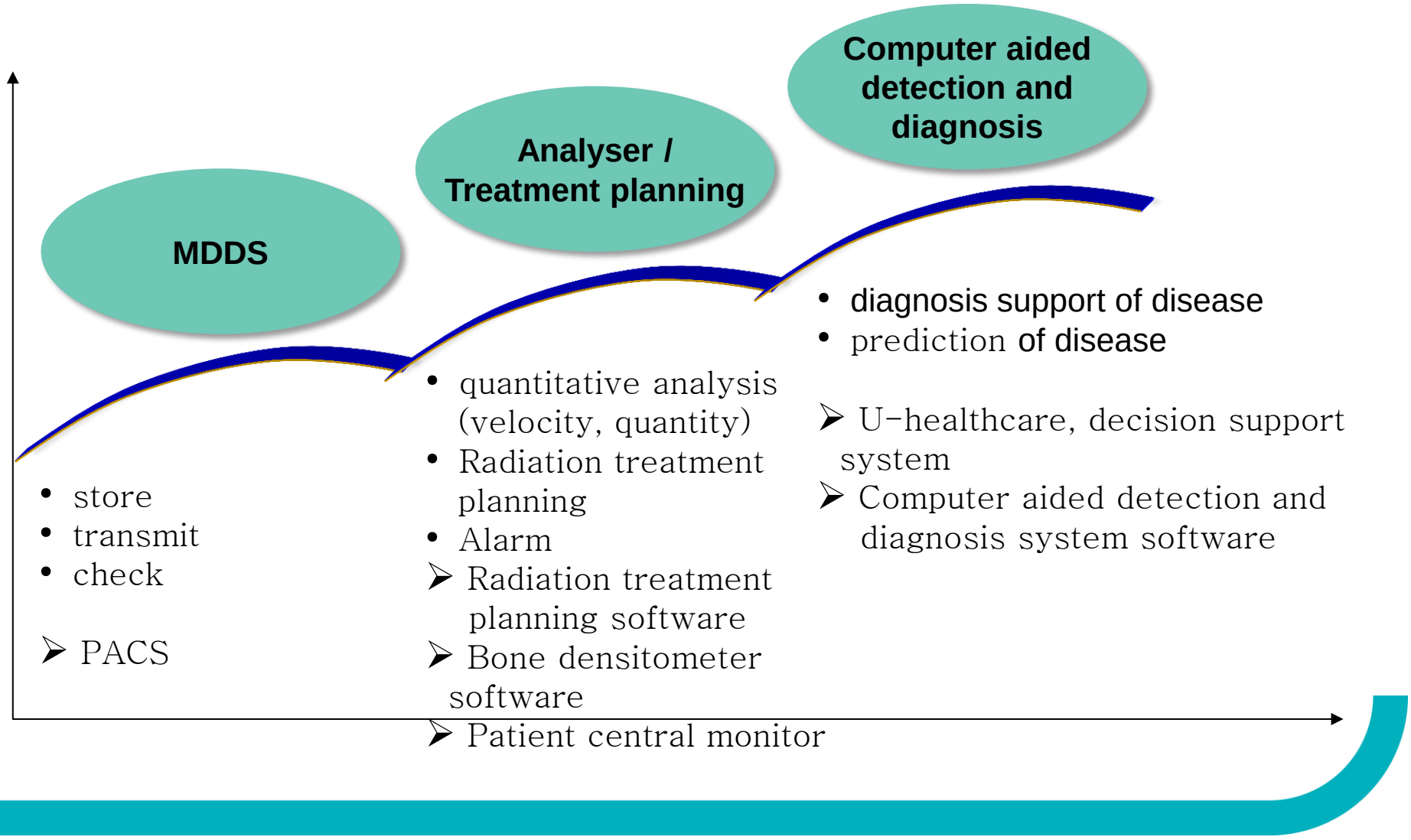
○ Apps that supplement tasks for health care facilities by automation(EMR, OCS, etc.)

○ Apps that help patients manage their health without providing patient-specific diagnosis, or treatment recommendations (getting optimal nutrition, maintaining a healthy weight, etc.)

Software as Medical device ?



Medical Device Software Development Trend



Regulation Necessity ?

○ Embedded or Stand-alone Software is responsible to play a key role to exhibit the performance of the medical device

- adversely affect safety and effectiveness of medical device by minor change due to its complexity and easy to change on software

* Risk of medical software : virus, malfunction, Interference between software(Japan, Research trend and challenges of medical software)

○ Increasing need to strengthen safety management in accordance with the increase in software product development that collect, store, manage, analyze, transmit the patient data

- Recently, various type of medical device has developed due to IT·BT·NT technological advancement
- Increasing development of medical application executed on a mobile platform, software for supporting clinical decision-making

○ Strengthening standard of safety management by adoption of IEC 60601-1 3rd Edition

- Adoption status : Class 4(’15.1.1), Class 3(’15.7.1), Class 2(’16.1.1), Class 1(’16.7.1)

How ?

○ To assure the safety and effectiveness of medical software, the manufacturer should

- Develop the performance and characteristics to meet all specifications and requirements of the user
- Require the management of its total life cycle from software development plan to sales of S/W

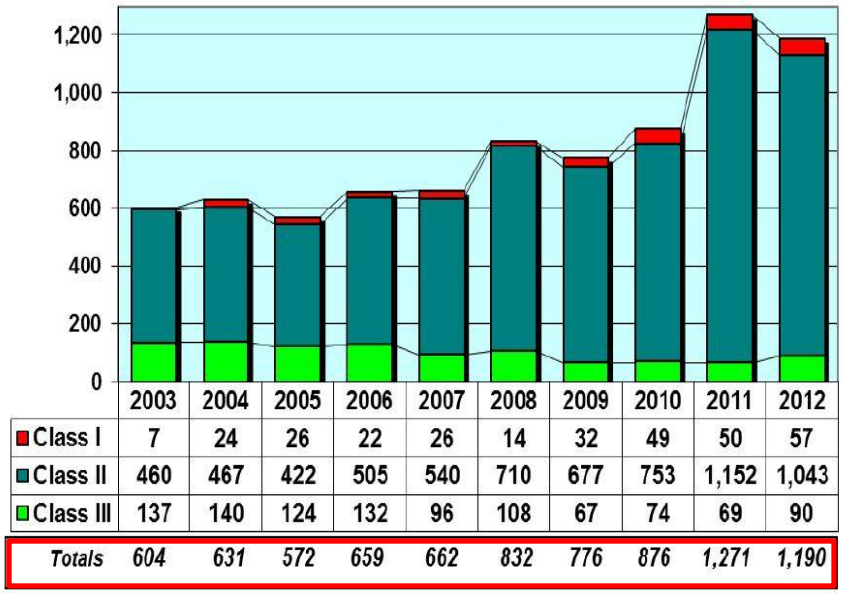
☞ Need management through a structured and planned approach

○ To confirm the assurance of safety and effectiveness of product, the Regulatory Authority should

- Adopting the approach that minimize company's burden due to the regulation
- Review data with scientific and law requirement to check whether it meet Safety and Efficacy or not

Need Internationally harmonized review process to establish **Safety and Efficacy** of Software as Medical Device

Recall status of medical device software in FDA



	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
Class I	7	24	26	22	26	14	32	49	50	57
Class II	460	467	422	505	540	710	677	753	1,152	1,043
Class III	137	140	124	132	96	108	67	74	69	90
Totals	*604*	*631*	*572*	*659*	*662*	*832*	*776*	*876*	*1,271*	*1,190*

Table 1. Class of MD vs Recall status in USFDA

	Software Change Control	Software Design	Software Design (manufacturing process)	Sum	% of all CDRH Recalls
2008	13	141	2	156	18.3%
2009	9	111	1	121	15.4%
2010	4	73	3	80	8.9%
2011	11	182	10	203	15.8%
2012	12	169	5	186	15.5%
Sum/Overall:	49	676	21	746	15.1%

Table 2. Recall status of software in USFDA('08~'12)

From : Medical Device Recall Report FY2003 to FY2012, FDA

Application state of medical software standard

IEC 60601-1 : 3rd Ed.
(2005.12.15)

Integration of some collateral standard (IEC 60601-1-n), Introduction of risk management

IEC 60601-1

- **Medical electrical equipment**

Part1 : General requirements for basic safety and essential performance

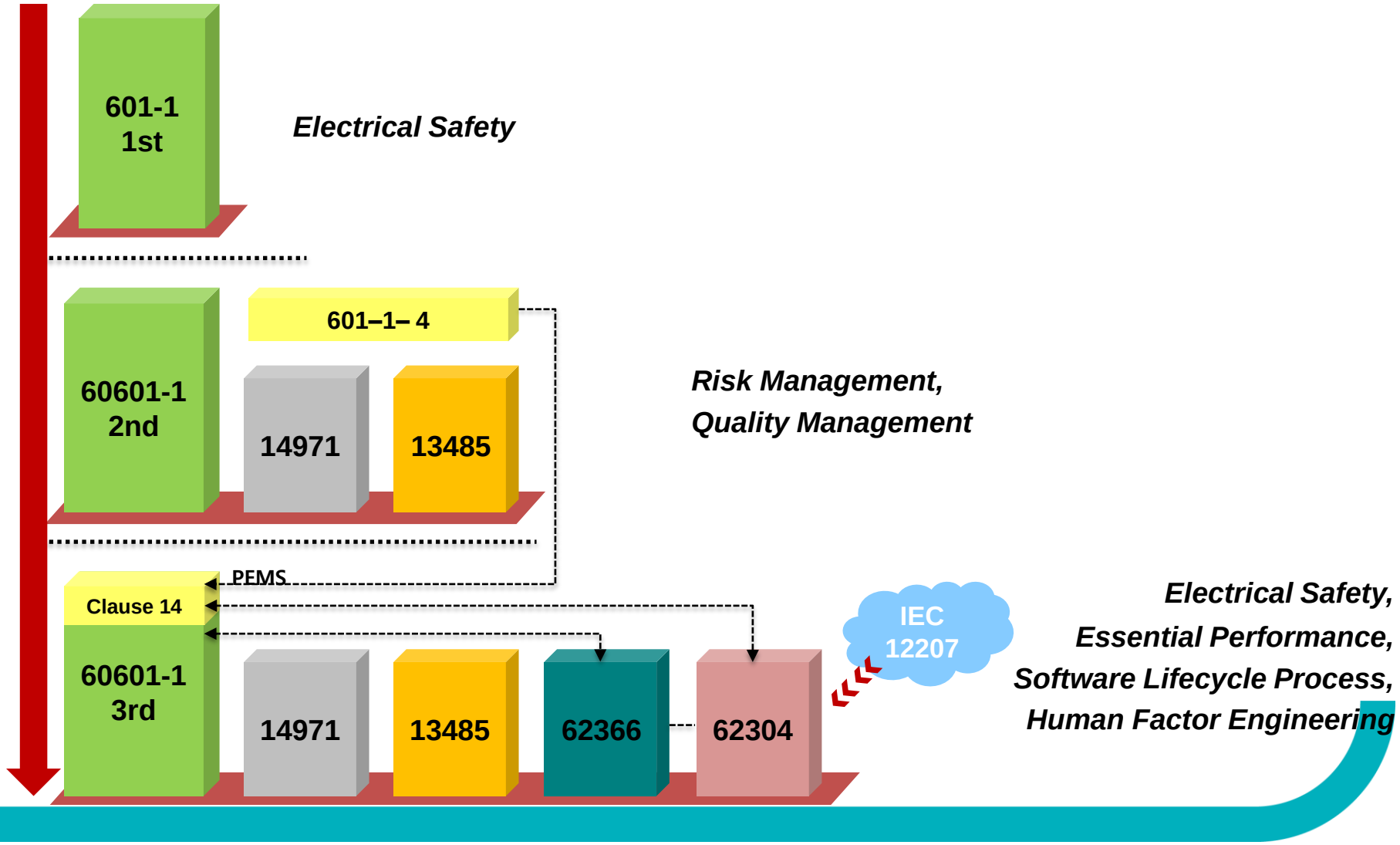
IEC 60601-1-n

- IEC 60601-1-1 (Medical electrical system)
- **IEC 60601-1-4 (PEMS, Programmable electrical medical system)**

ISO 14971

- **Risk management**

Application state of medical software standard



IEC 60601-1 3rd ed./Programmable electrical medical system(PEMS)

- All the requirements concerning risk management(IEC 60601-1-4) included to IEC 60601-1 3rd according to requiring ISO 14971 standard

- Need Risk analysis that determine applicability of requirement in PEMS

14. Programmable electrical medical system
  14.1 General
  14.2 Documentation
  14.3 RISK MANAGEMENT plan
  14.4 PEMS DEVELOPMENT LIFE
  14.5 Problem resolution
  14.6 RISK MANAGEMENT PROCESS
  14.7 Requirement specification
  14.8 Architecture
  14.9 Design and implementation
  14.10 VERIFICATION
  14.11 PEMS VALIDATION
  14.12 Modification
  14.13 PEMS intended to be incorporated into an IT-NETWORK

Need to apply IEC 62304

* IEC 62304 : Medical device software Software life cycle processes

IEC 60601-1 3rd ed./Programmable electrical medical system(PEMS)

General Requirement | Software Development | Software Maintenance | Software Risk Management | S/W Config. Management | S/W Problem Resolution


NORME INTERNATIONALE
INTERNATIONAL STANDARD

CEI IEC 62304

Première édition
First edition
2006-05

Logiciels de dispositifs médicaux – Processus du cycle de vie du logiciel

Medical device software – Software life cycle processes

IEC ISO

Numéro de référence
Reference number
CEI/IEC 62304:2006

Medical Device Software – Software Life Cycle Process

One General Requirements, Five Processes.

There is no known method to guarantee 100% SAFETY for any kind of software.

There are three principles which promote SAFETY for MEDICAL DEVICE SOFTWARE

- *Risk Management;*
- *Quality management;*
- *Software engineering.*

Guidelines for medical device software

US

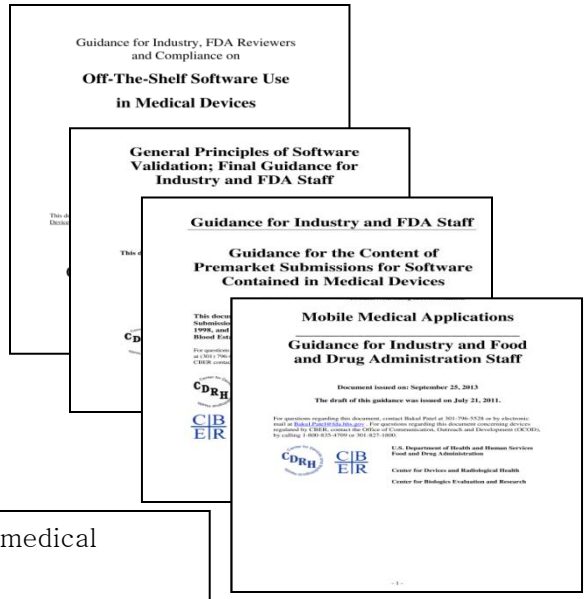
FDA

Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical
Devices

General Principles of Software Validation; Final Guidance for Industry and FDA Staff

Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

Mobile Medical Applications Guidance for Industry and Food and Drug Administration Staff



EU

GUIDELINES ON THE QUALIFICATION AND CLASSIFICATION OF
STAND ALONE SOFTWARE USED IN HEALTHCARE WITHIN THE REGULATORY FRAMEWORK OF MEDICAL DEVICES

Guidance on medical device stand-alone software (including apps)


EUROPEAN COMMISSION
DG HEALTH AND CONSUMER
Directorate B, Unit B2 "Health Technology and Cosmetics"

MEDICAL DEVICES: Guidance document

Qualification and Classification of stand alone software

MEDDEV 2.1/6
January 2012

GUIDELINES ON THE QUALIFICATION AND CLASSIFICATION OF STAND ALONE SOFTWARE USED IN HEALTHCARE WITHIN THE REGULATORY FRAMEWORK OF MEDICAL DEVICES

Foreword

The present guidelines are part of a set of guidelines relating to questions of application of the EU legislation on medical devices. They are legally not binding.

The guidelines have been carefully drafted through a process of consultation of the various interested parties (Competent Authorities, Commission services, industry and Notified Bodies in the medical device sector) during which intermediate drafts were circulated and comments were taken up in the document where appropriate.

Therefore this document reflects positions taken in particular by the aforementioned interested parties.

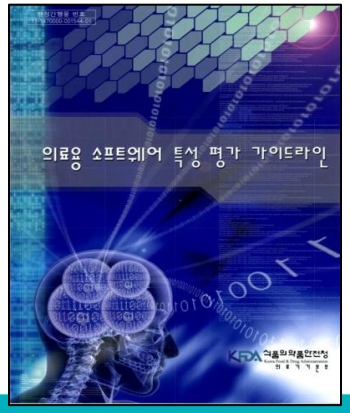
Due to the participation of the aforementioned interested parties, it is anticipated that these guidelines will be followed within the Member States and, therefore, ensure uniform application of relevant Directive provisions.

MFDS

Guidelines for approval and review of medical device software

Guidelines for evaluating characteristics of medical device software

Guidelines for software validation of medical device



Existing Technical document and Attached document

Shape and structure	Structure or algorithm, main function, etc. of software
Raw materials	Model name or name, version, operating environment, etc. of software
Method of use	Method of use for the function including screen picture that identify main function of program
Test standard	Test standard that identify main function of software

Attached document

- **Data of confirming model name or name, version, operating environment, structure, etc.** (Software requirement specification, development specification, instructions for use, product catalog, etc.)
- **Data for performance : validation and effectiveness data**

Revision : Notice for approval, notification, review of medical device

Article 9 (Shape and Structure)

Before

○ Article 9(Shape and Structure) Shape and structure shall be described as follows

2. Regardless item1 in case of using electric · mechanical mechanism, shall describe following information

8. Structure of embedded software or algorithm and major function

(except embedded software that is not intended for diagnose·measure·analyze and so on)

After

○ Article 9(Shape and Structure) Shape and structure shall be described as follows

2. Regardless item1 in case of using electric · mechanical mechanism, shall describe following information

8. Structure of software and major function

Revision : Regulation for approval, notification, review of medical device

Article10 (Material)

Before

○ Article 10(Material) Material shall be described as follows

2. In case of instrument and machine using electric, shall describe following information

7. If software is embedded or stand-alone to Medical Device, Model name of software or name, version and operation system according to item 1

After

○ Article 10(Material) Material shall be described as follows

2. In case of instrument and machine using electric, shall describe following information

7. If software is used, according to item1, software name, version shall be described on standard or characteristic column and if used as stand-alone, operating system shall be described in addition

Revision : Regulation for approval, notification, review of medical device

Article29
(Requirements on Attached Documents)

Before

○ Article29(Requirements on Attached Documents) ① Attached Documents for technical review requirements are as follows

8. Documents for performance

1. General

(….) In case of embedded software or stand-alone software, documents shall be provided that can verify major function including software model name or name, version, operating system, structure. (….)

After

○ Article29(Requirements on Attached Documents) ① Attached Documents for technical review requirements are as follows

8. Documents for performance

1. General

(….) In case of embedded software or stand-alone software, Conformity report and verification & Validation data shall be submitted according to form No.13*(….)*

Revision : Regulation for approval, notification, review of medical device

<Form No.13>

의료기기 소프트웨어 적합성 확인보고서			
품목명 (품목분류번호)		**소프트웨어 명칭 및 버전**	
소프트웨어 사용형태	☐ 내장형	☐ 독립형	
소프트웨어 기능적 특성 (중복선택 가능)	☐ 제어 ☐ 진단 ☐ 데이터 수신	☐ 측정 ☐ 데이터 변환 ☐ 표시	☐ 분석 ☐ 데이터 전송 ☐ 기타
소프트웨어 안전성 등급	☐ A	☐ B	☐ C
소프트웨어 사용목적			
소프트웨어 운영환경 (독립형 소프트웨어에 한함)			
소프트웨어 개발	**소프트웨어 개발 계획**		
	소프트웨어 요구사항 분석		
	소프트웨어 구현		
	소프트웨어 검증 및 유효성확인		
	소프트웨어 배포		
소프트웨어 유지보수 및 문제해결			
소프트웨어 위험관리			
소프트웨어 형상관리			

Contents of technical document

Category		Contents	Subject
Shape and structure	Structure	Writing explanation and diagram by dividing into function module unit from medical device software in order to grasp the inside structure of medical device software	Medical device software
	Main function	Writing explanation about main function of medical device software that defined according to intended used	
Raw materials	Name	Writing name of medical device software	Medical device software
	Version	Writing version of medical device software	
	Operating environment	Writing requirement of hardware that normally operates medical device software	Stand-alone software
Method of use		Writing method of use about main function with user screen picture including explanation of each category(result output element) in the user screen of medical device software	Medical device software including user screen interface

Changed on review process for SaMD

- ✓ More simple and clarified
- ✓ Required documents have been Minimized even regulation is enforced

	2014년	2015.7.29
Contents	• **Shape and structure** (Structure or algorithm, main function) • Raw materials (Model name or name, version, operating environment) • **Method of use** (Explaining main function with screen picture)	• **Shape and structure** (Structure, main function) • Raw materials (name, version, operating environment(Including stand-alone SW)) • **Method of use** (Explaining main function with screen picture)
Attached document	• **Software requirement specification** • **Development specification** • **Verification and Validation data** • **Instructions for use, product catalog, etc.**	• **Conformity Report(1p)** • **Verification and Validation data**

Thank you

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