ภาพรวมการทดสอบซอฟต์แวร์เครื่องมือแพทย์ผ่าน IEC 62304

(Overview of medical device software testing through IEC 62304)

ดร. พนิตา เมนะเนตร
ห้องปฏิบัติการทดสอบซอฟต์แวร์และระบบซอฟต์แวร์เป็นส่วนประกอบ (SQUAT)
กลุ่มงานวิศวกรรมซอฟต์แวร์และทดสอบผลิตภัณฑ์ (SEPT)
ฝ่ายสนับสนุนบริการทางวิศวกรรมและเทคโนโลยี (TSS)
ศูนย์เทคโนโลยีอิเล็กทรอนิกส์และคอมพิวเตอร์แห่งชาติ (NECTEC)

หัวข้อ (Topics)

- Eco System for Quality Digital Product
- Related Standard in Medical Device
- Terminology
  - PEMS, PESS
  - SDLC – V Model
- IEC60601-1 Cl.14
- IEC62304
- Case Studies
- Summary

กระบวนการนำผลิตภัณฑ์ดิจิทัลที่มีคุณภาพสู่ผู้บริโภค

ผู้ประกอบการ
(นำเข้า/ส่งออก)
ผลิตภัณฑ์ดิจิทัล

+

มาตรฐาน
- ต่างประเทศ
- ในประเทศ

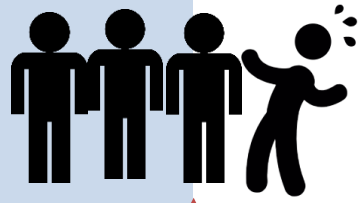
มาตรฐาน
บังคับ
ตปท

Testing LAB

LAB ทดสอบที่มีมาตรฐาน

Certified Body

หน่วยรับรอง

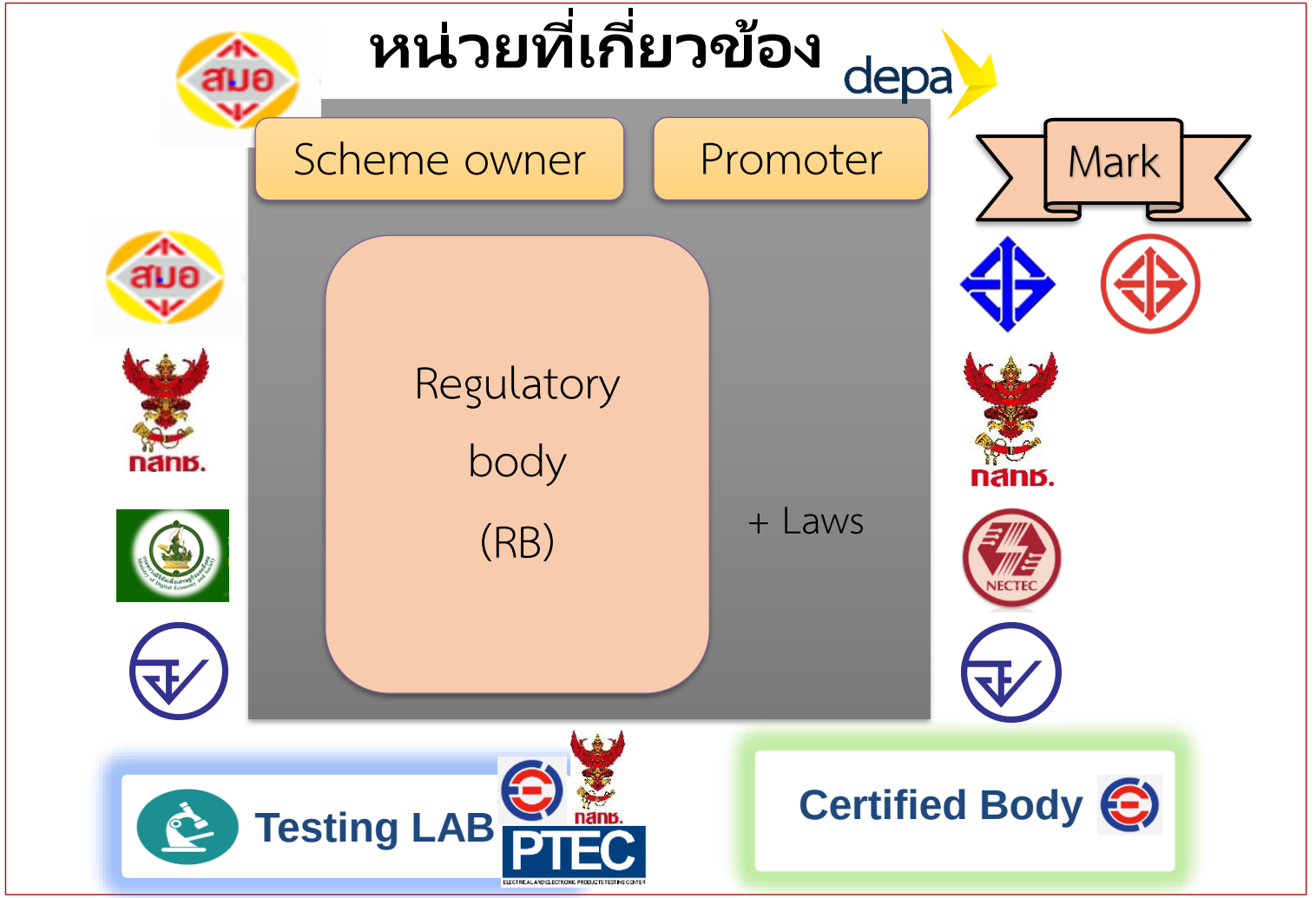


ผู้บริโภค

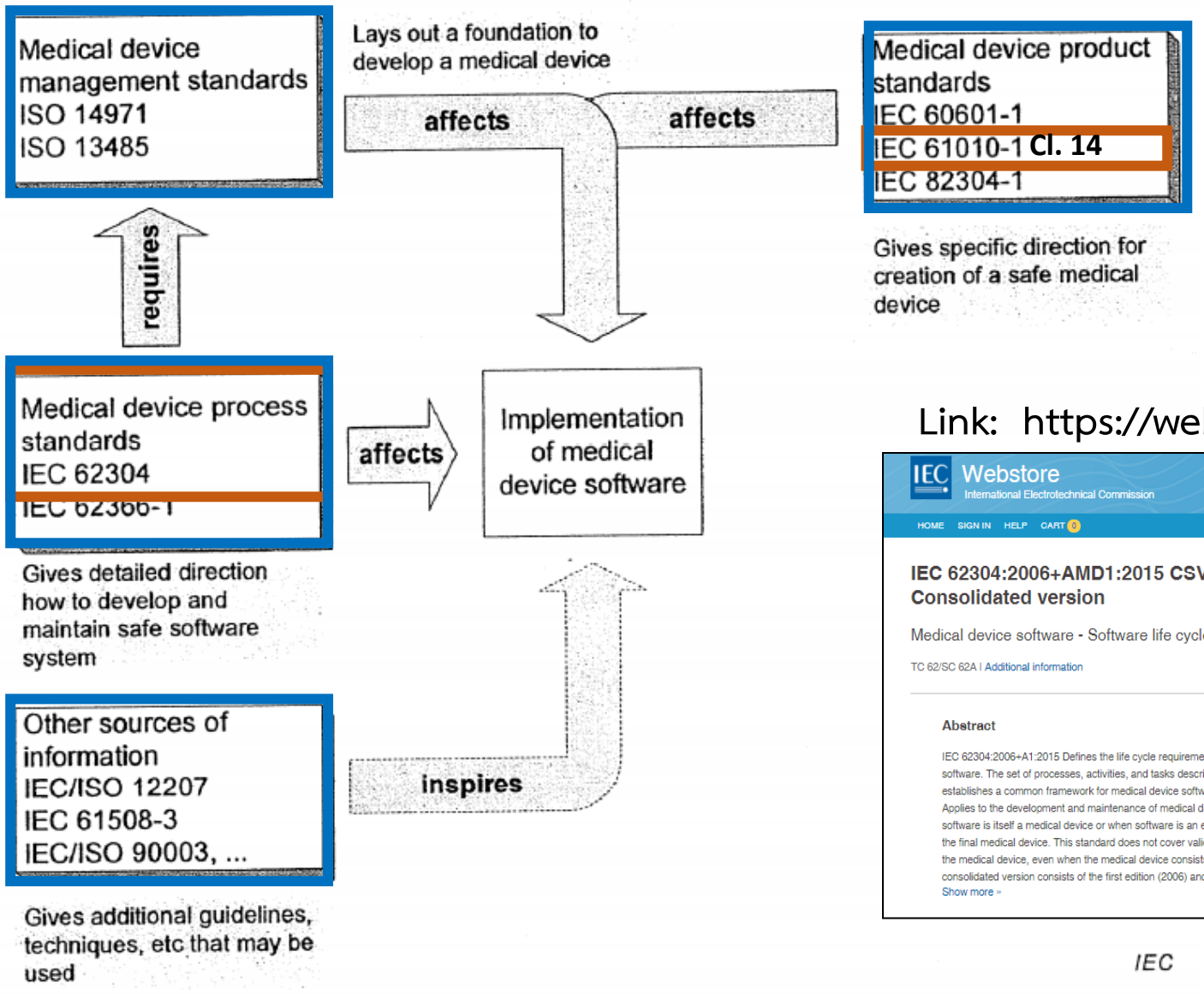
<u>หมายเหตุ</u> เส้นสีดำ – กระบวนการสากล เส้นสีแดง - กระบวนการปัจจุบัน

Eco System for Quality Digital Product

ระบบนิเวศน์คุณภาพผลิตภัณฑ์ดิจิทัล

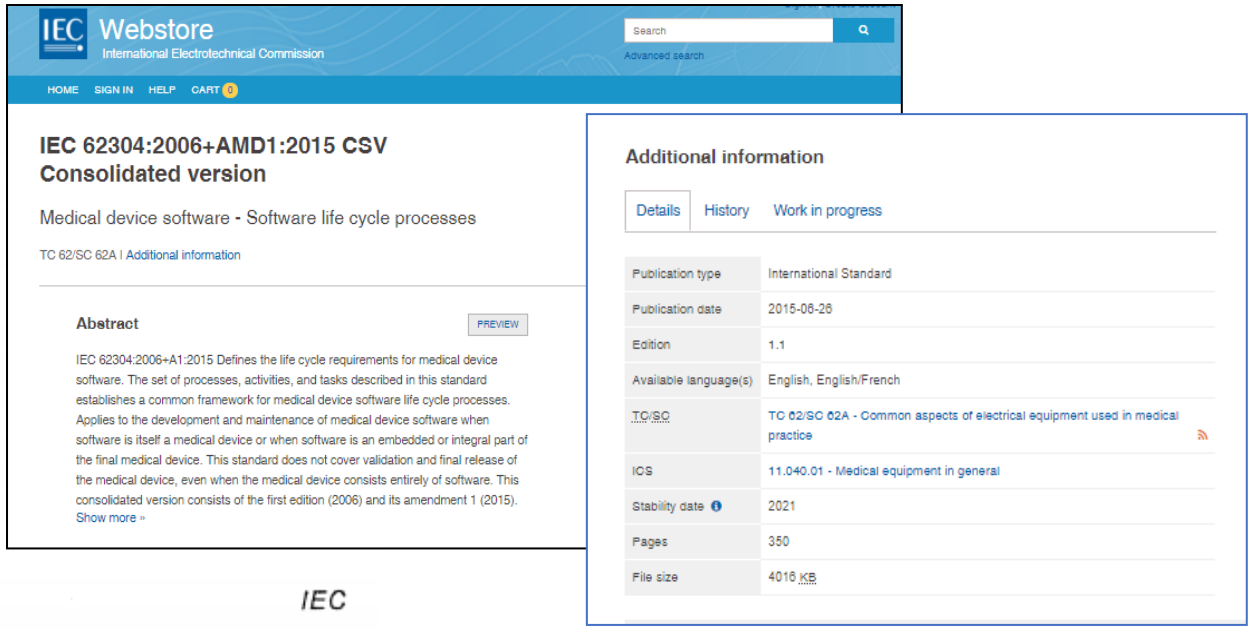


Related Standards in Medical Device



Standards for software medical device
IEC 60601-1 : 2005 + AMD1:2012 Cl.14
IEC 62304 : 2006 + AMD1:2015

Link: https://webstore.iec.ch/publication/22794



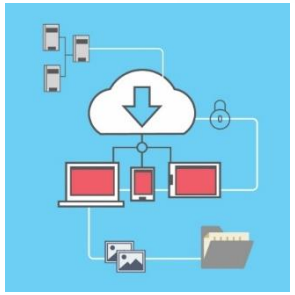
IEC

What is a Software?

What is SOFTWARE ?

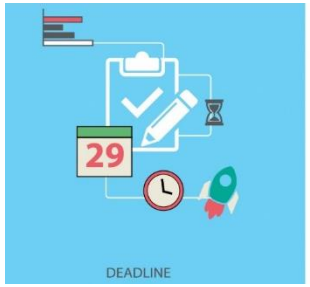
[ISO/IEC12207:2008] **Software is**

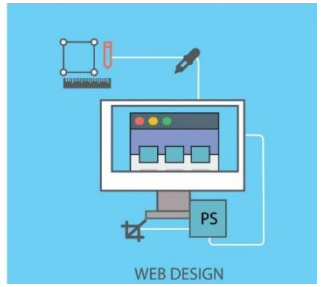
1) Instruction (computer programs) that when executed provide desired features, function, and performance



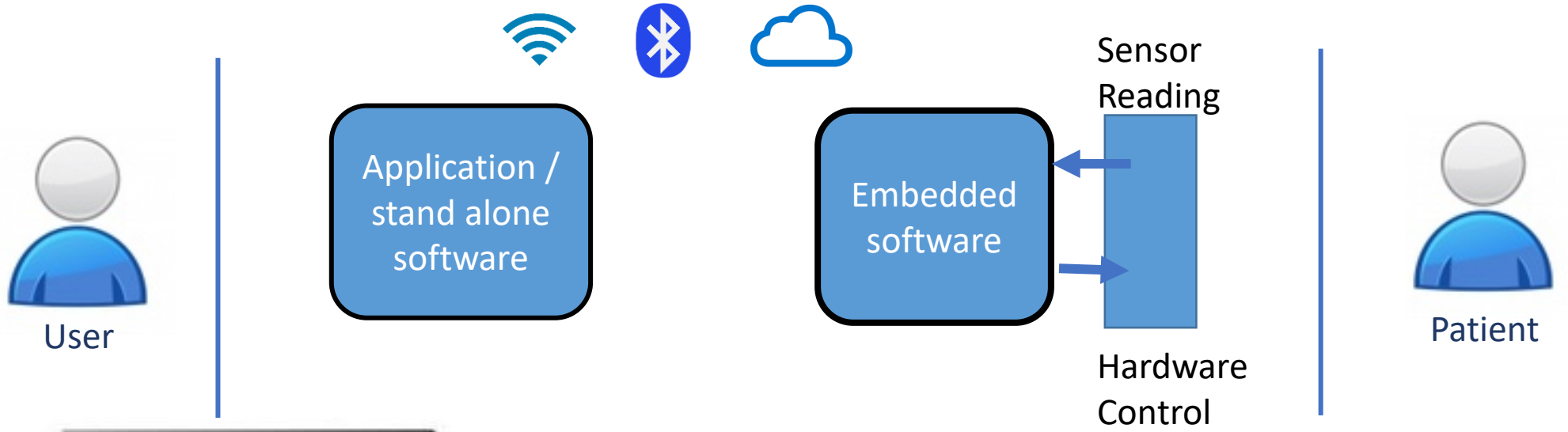
2) Data structure that enable the programs to adequately manipulate information

3) Descriptive information in both hard copy and virtual forms that describes the operation and use of the programs





Software Types

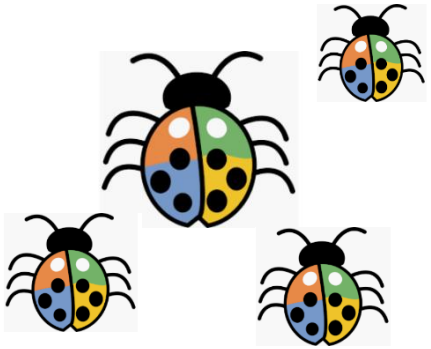


Infusion Pump

Software Engineering Overview – Part 1 : Problem

Delivery late

High cost



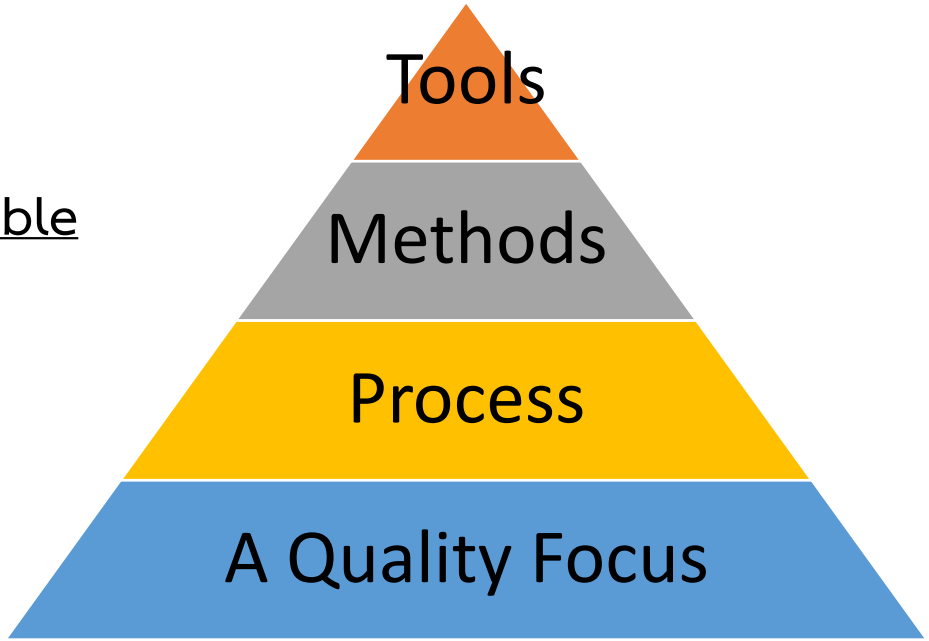
Low Quality

Software Engineering Overview

Software Engineering

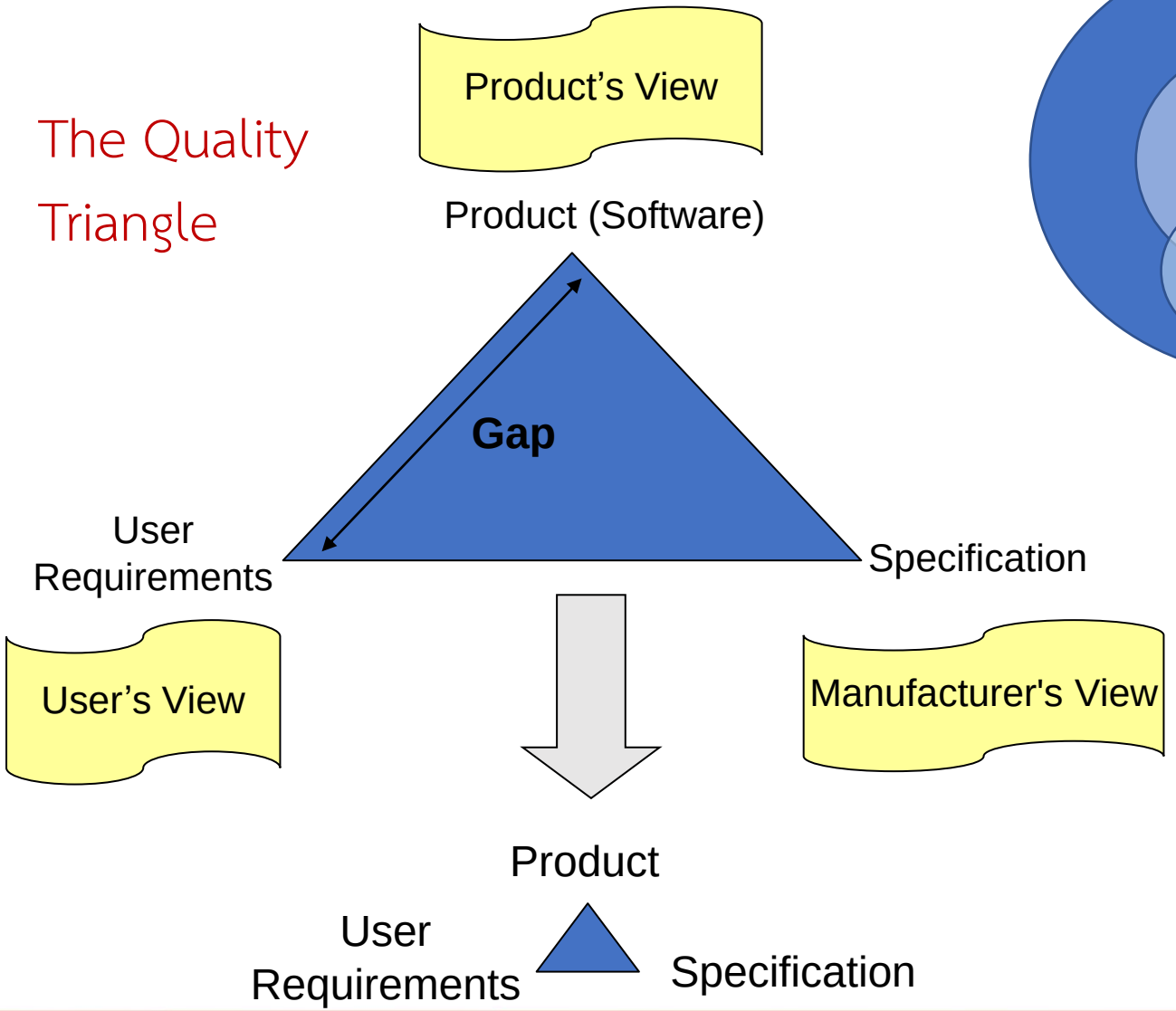
1) The application of a systematic, disciplined, quantifiable approach to the development, operation, and maintenance of software; that is the application of engineering to software.

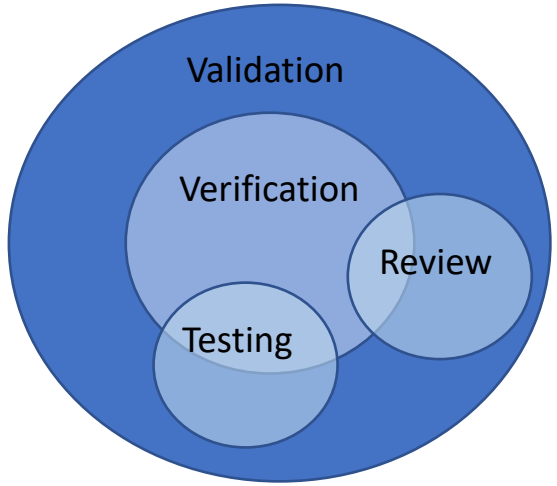
2) The study of approaches as in (1).



Software Engineering – Software Quality Management

The Quality Triangle





Validation

- user requirement
- external view of quality
- **correct product** has been built
- Good product

Verification

- work product
- internal view of quality
- product has been **built correctly**
- Good process

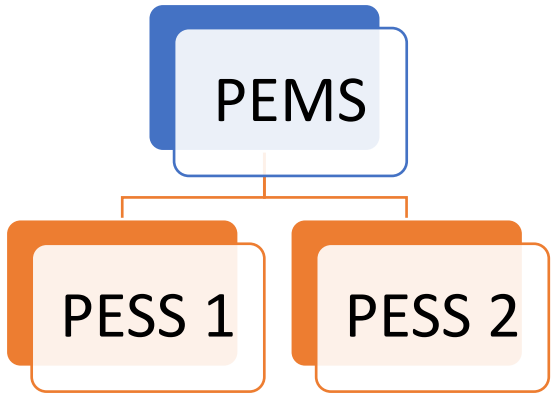
Software IEC 60601-1 Cl.14 vs IEC 62304

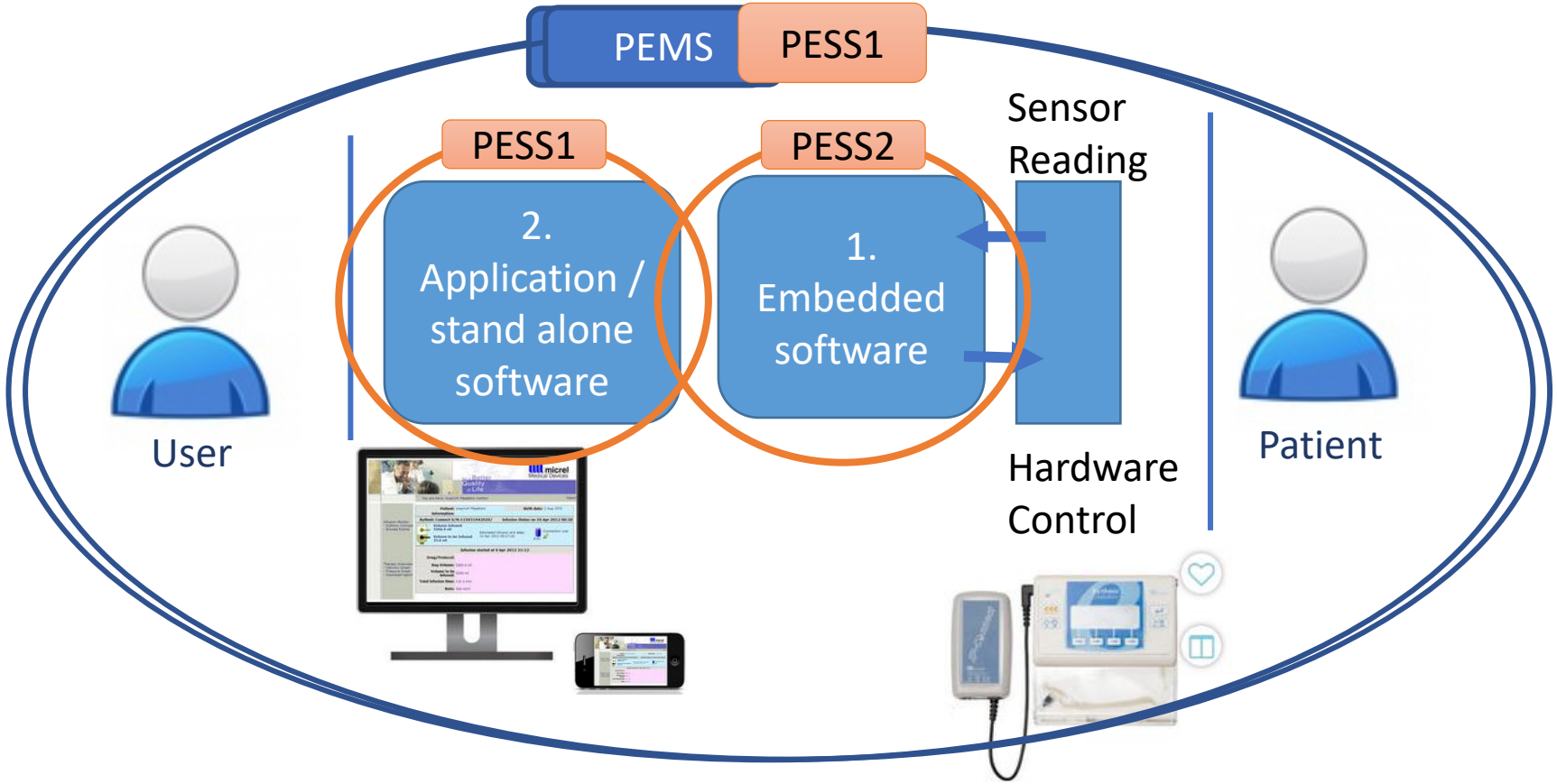
- **PEMS - programmable electrical medical systems**

  ME EQUIPMENT or an ME SYSTEM containing one or more PROGRAMMABLE ELECTRONIC SUBSYSTEMS (PESS)

- **PESS – programmable electrical SubSystems**

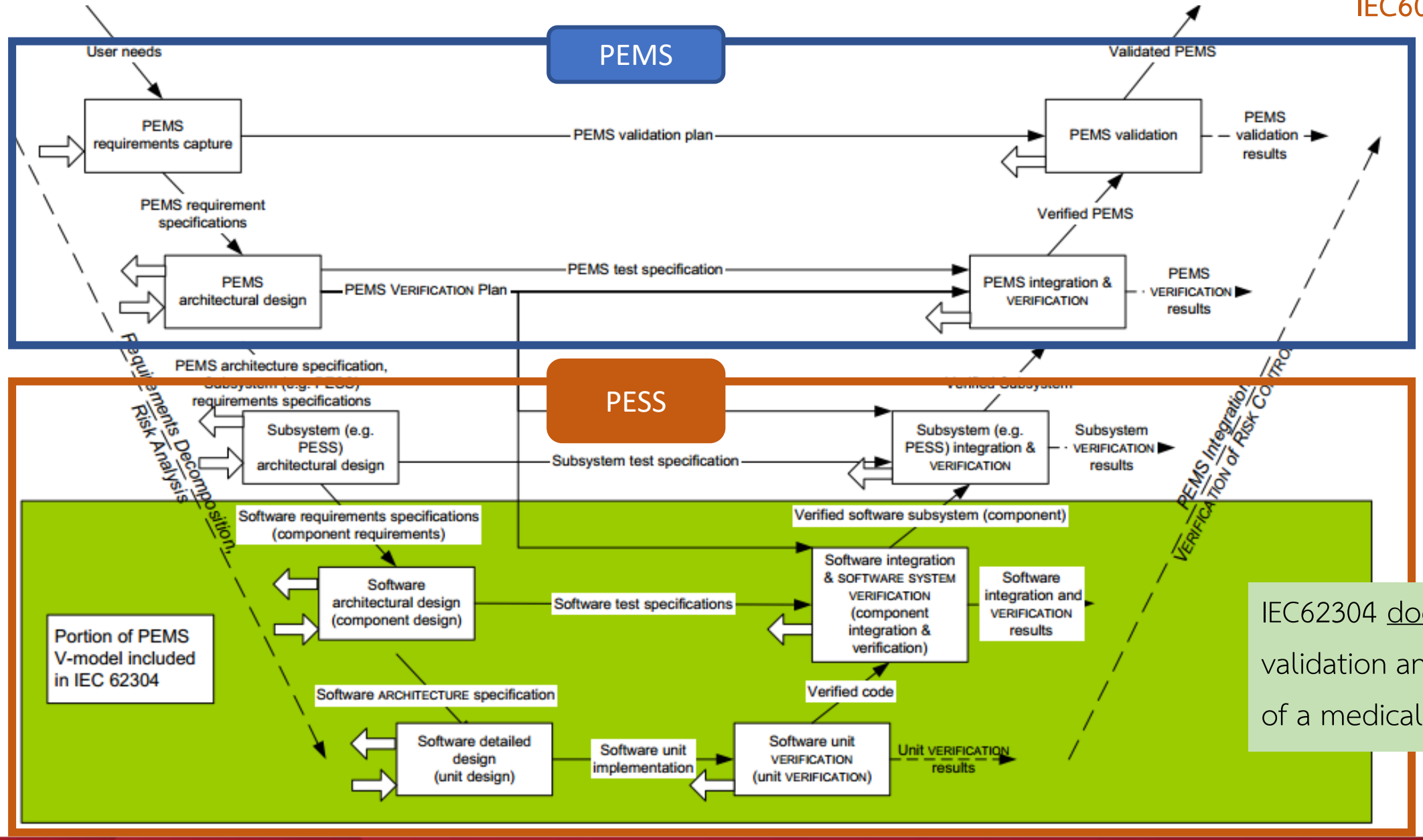
  system based on one or more central processing units, including their software and interfaces





Software IEC 60601-1 Cl.14 vs IEC 62304

IEC60601-1 Cl. 14



IEC62304 does not cover validation and final release of a medical device

Software IEC 60601-1 Cl.14 vs IEC 62304

IEC 60601-1 : 2005 + AMD1:2012 Cl.14

14	*** Programmable electrical medical systems (PEMS)**
14.1	* General
14.2	* Documentation
14.3	* Risk management plan
14.4	* PEMS development life-cycle
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	* Connection of PEMS by network/data coupling to other equipment

Example: IEC 60601-1 : 2005 + AMD1:2012 Cl.14 Test Report

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
14	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)		
14.1	Requirements in 14.2 to 14,12 not applied to PEMS when it provides no functionality necessary for BASIC SAFETY or ESSENTIAL PERFORMANCE, or		
	- when application of RISK MANAGEMENT showed that failure of PESS does not lead to unacceptable RISK .....:		
	RISK MANAGEMENT FILE contains an assessment of RISKS associated with the failure of the PESS: (ISO 14971 Cl. 4.2-4.4, 5)		
	Requirements of 14.13 not applied to PEMS intended to be incorporated into an IT NETWORK		
	When the requirements of 14.2 to 14.13 apply, the requirements of IEC 62304:2006 clause 4.3, 5, 7, 8 and 9 apply for the development or modification of software of each PESS		
	Software development process for Software Classification applied in accordance with Clause 4.3 of IEC 62304 .....:		
	Software development process applied according to Clause 5 of IEC 62304 .....:		
	Software development process for Software risk management applied according to Clause 7 of IEC 62304.....:		
	Software development process Configuration Management applied according to Clause 8 of IEC 62304 .....:		
	Software development process for Software Problem Resolution applied according to Clause 9 of IEC 62304.....:		

Ref : *Medical electrical equipment—Part1 General Requirement for basic safety and essential performance*, IEC 60601-1 : 2005 + AMD1: 2012

Medical Device Process Standard IEC62304

Clause and subclauses \ Class	
4	GENERAL REQUIREMENTS [A,B,C]
4.1	Quality management system
4.2	Risk management
4.3	Software safety classification
4.4	Legacy software
5	SOFTWARE DEVELOPMENT PROCESS
5.1	Software development planning
5.2	Software requirements analysis (SRS)
5.3	Software architectural design
5.4	Software detailed design
5.5	Software unit implementation
5.6	Software integration and integration testing
5.7	Software system testing
5.8	Software release for utilization at a system level

Clause and subclauses \ Class	
6	SOFTWARE MAINTENANCE PROCESS [A,B,C]
6.1	[A, B, C] software maintenance plan
6.2	Problem and modification analysis
6.3	Modification implementation
7	SOFTWARE RISK MANAGEMENT PROCESS
7.1	Analysis of software contributing to hazardous situations
7.2	Risk control measures
7.3	Verification of risk control measures
7.4	**[A, B, C]** Risk management of software changes
8	SOFTWARE CONFIGURATION MANAGEMENT PROCESS [A,B,C]
8.1	Configuration identification
8.2	Change control
8.3	[A, B, C] Configuration status accounting

Clause and subclauses \ Class	
9	SOFTWARE PROBLEM RESOLUTION PROCESS [A,B,C]
9.1	Prepares a problem report
9.2	Investigate problem
9.3	Advises relevant parties
9.4	Use change control process
9.5	Maintains records
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9.7	Verify problem resolutions
9.8	Test documentation content

IEC 62304 : 2006 + AMD1:2015

Medical Device Process Standard IEC62304

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ISO14971

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IEC 62304 : 2006 + AMD1:2015

Software Safety Classification

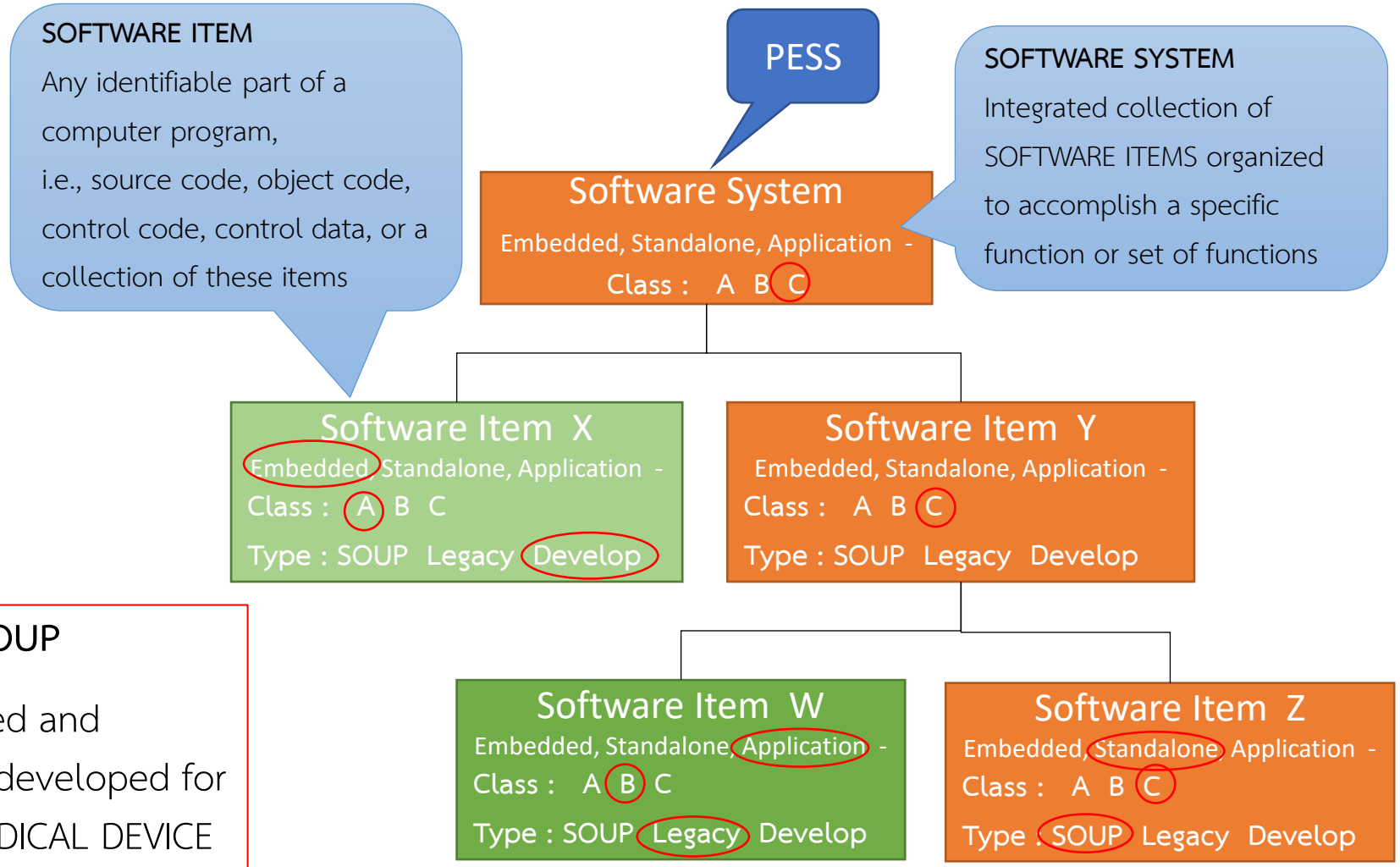
Definition : Software item Types

- **Legacy Software**

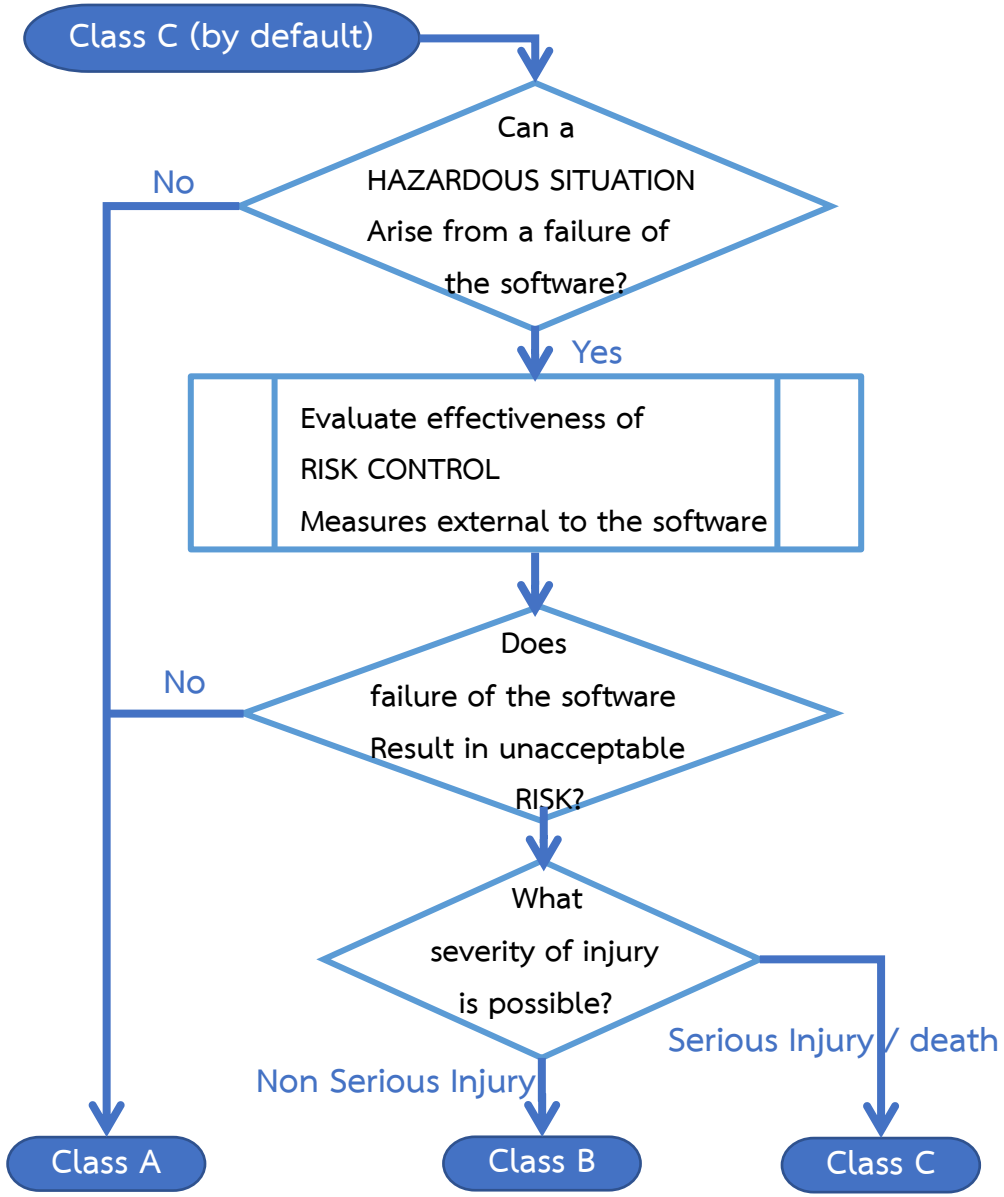
MEDICAL DEVICE SOFTWARE which was legally **places on the market and is still market today** but for which there is insufficient objective evidence that it was developed in compliance with the current version of this standard.

- **Software of unknown provenance – SOUP**

SOFTWARE ITEM that is already developed and generally available and that has not been developed for purpose of being incorporated into the MEDICAL DEVICE **[off – the – self software] or** SOFTWARE ITEM previously developed for which adequate records of the develop PROCESSES are not available.



Software Safety Classification



In determining the software safety classification of the SOFTWARE SYSTEM:

- Probability of a software failure shall be assumed to be 1.
- Only RISK CONTROL measures not implemented within (external to) the SOFTWARE SYSTEM shall be considered.

NOTE: Such RISK CONTROL measures may reduce the probability that a software failure will cause HARM, and/or the severity of that HARM.

NOTE: A SOFTWARE which implements RISK CONTROL measures may fail, and this may contribute to a HAZARDOUS SITUATION.

The resulting HARM may include the harm which the RISK CONTROL measures is designed to prevent (see 7.2.2b)

- The software safety classes shall initially be assigned based on severity as follows:
  Class A: No injury or damage to health is possible
  Class B: Non-SERIOUS INJURY is possible
  Class C: Death or SERIOUS INJURY is possible”

Figure 3 – Assignment software safety classification

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Example: IEC62034 Test Report : Safety Classification

IEC 62304			
Clause	**Requirement - Test**	**Result - Remark**	**Verdict**
4	**GENERAL REQUIREMENTS**		—
4.1	**[A, B, C] Quality management system**		—
	The MANUFACTURER of MEDICAL DEVICE SOFTWARE demonstrates the ability to provide MEDICAL DEVICE SOFTWARE that consistently meets customer requirements and applicable regulatory requirements		
4.2	**[A, B, C] RISK MANAGEMENT**		—
	The MANUFACTURER applies a RISK MANAGEMENT PROCESS complying with ISO 14971		
4.3	**[A, B, C] Software safety classification**		—
	a) The MANUFACTURER assigns to each SOFTWARE SYSTEM a software safety class according to the RISK of HARM to the patient, operator, or other people resulting from a HAZARDOUS SITUATION to which the SOFTWARE SYSTEM can contribute in a worst-case-scenario		
	The SOFTWARE SYSTEM is software safety class A if:		—
	- the SOFTWARE SYSTEM not contribute to a HAZARDOUS SITUATION; or		
	- the SOFTWARE SYSTEM contribute to a HAZARDOUS SITUATION which does not result in unacceptable RISK after consideration of RISK CONTROL measures external to the SOFTWARE SYSTEM		
	The SOFTWARE SYSTEM is software safety class B if:		—
	- the SOFTWARE SYSTEM contribute to a HAZARDOUS SITUATION which results in unacceptable RISK after consideration of RISK CONTROL measures external to the SOFTWARE SYSTEM and the resulting possible HARM is non-SERIOUS INJURY		

IEC 62304			
Clause	**Requirement - Test**	**Result - Remark**	**Verdict**
	The SOFTWARE SYSTEM is software safety class C if:		—
	- the SOFTWARE SYSTEM contribute to a HAZARDOUS SITUATION which results in unacceptable RISK after consideration of RISK CONTROL measures external to the SOFTWARE SYSTEM and the resulting possible HARM is death or SERIOUS INJURY		
	For a SOFTWARE SYSTEM initially classified as software safety class B or C, the MANUFACTURER has implemented additional RISK CONTROL measures external to the SOFTWARE SYSTEM and subsequently has assigned a new software safety classification to the SOFTWARE SYSTEM		
	c) The MANUFACTURER documents the software safety class assigned to each SOFTWARE SYSTEM in the RISK MANAGEMENT FILE		
	d) When a SOFTWARE SYSTEM is decomposed into SOFTWARE ITEMS, and when a SOFTWARE ITEM is decomposed into further SOFTWARE ITEMS, such SOFTWARE ITEMS inherit the software safety classification of the original SOFTWARE ITEM (or SOFTWARE SYSTEM) unless the MANUFACTURER documents a rationale for classification into a different software safety class		
	A rationale explains how the new SOFTWARE ITEMS are segregated so that they may be classified separately		
	e) The MANUFACTURER documents the software safety class of each SOFTWARE ITEM if that class is different from the class of the SOFTWARE ITEM from which it was created by decomposition		
	f) When applied to a group of SOFTWARE ITEMS, the MANUFACTURER uses the PROCESSES and TASKS which are required by the classification of the highest-classified SOFTWARE ITEM in the group unless the MANUFACTURER documents in the RISK MANAGEMENT FILE a rationale for using a lower classification		
	g) Class C requirements apply for each SOFTWARE SYSTEM, until a software safety class is assigned		

Ref : Ref : *Medical Device Software—Software Life Cycle Processes*, ANSI/AAMI/IEC 62304 : 2006 + AMD : 2015.

Summary of requirements by software safety class

Clause and subclauses \ Class		A	B	C
Clause 4	**All requirements**	X	X	X
5.1 (Plan)	**5.1.1, 5.1.2, 5.1.3, 5.1.4, 5.1.5, 5.1.6, 5.1.7, 5.1.8, 5.1.9 (development, integration, testing, verification, risk management, documentation, configuration)**	X	X	X
	5.1.5, 5.1.10, 5.1.11, 5.1.12 (integration, supporting item, CI before verification, software defect)		X	X
	5.1.4 (Software development standards, methods and tools planning)			X
5.2 (Requirement)	**5.2.1, 5.2.2, 5.2.4, 5.2.5, 5.2.6 (define & document SRS, content, re-evaluate, update, verify)**	X	X	X
	5.2.3 (Risk control measure)		X	X
5.3 (Architectural)	5.3.1, 5.3.2, 5.3.3, 5.3.4, 5.3.6		X	X
	5.3.5 (identify segregation necessary for risk control)			X
5.4 (Detail design)	5.4.1 (subdivide software into software units)		X	X
	5.4.2, 5.4.3, 5.4.4 (develop detail design for each software unit & interfaces, verify detail design)			X
5.5 (Implementation)	**5.5.1 (implementation each software unit)**	X	X	X
	5.5.2, 5.5.3, 5.5.5 (software unit acceptance criteria, verification)		X	X
	5.5.4 (additional software unit acceptance criteria)			X

Summary of requirements by software safety class

Clause and subclauses \ Class		A	B	C
5.6 (Integration and Integration Testing)	All requirements		X	X
5.7 (System testing)	**All requirements**	X	X	X
5.8 (Release)	**5.8.1, 5.8.2, 5.8.4, 5.8.7, 5.8.8**	X	X	X
	5.8.3, 5.8.5, 5.8.6		X	X
Clause 6 (Maintenance)	**All requirements**	X	X	X
7.1 (Analysis of software contributing to hazardous situations)	All requirements		X	X
7.2 (Risk control measure)	All requirements		X	X
7.3 (Verification of risk control measures)	All requirements		X	X
7.4 (Risk management of software changes)	**7.4.1**	X	X	X
	7.4.2, 7.4.3		X	X
Clause 8 (Configuration)	**All requirements**	X	X	X
Clause 9 (Problem resolution)	**All requirements**	X	X	X

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ISO14971

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IEC 62304 : 2006 + AMD1:2015

Medical Device Process Standard IEC62304

: Software Risk Management Process

ISO 14971: 2019

Risk = Prob x Severity

<u>แหล่งกำเนิด</u>

สภาพเงื่อนไขที่อาจจะเป็นสาเหตุที่ทำให้เกิดอันตราย เช่น ไฟฟ้า เชื้อแบคทีเรีย

<u>ลำดับเหตุการณ์</u>

เช่น หนูกัด ปลั๊กเสีย

<u>สถานการณ์ที่นำไปสู่อันตราย</u>

เช่น ไฟฟ้ารั่ว ถุงบรรจุขาด

Hazard → Sequence of events → Hazard situation → Harm (Impact)

Probability of occurrence of harm

Severity of harm

<u>ความถี่ หรือโอกาสที่เกิด</u>

เช่น เกิดบ่อย นานๆเกิดที ไม่เคยเกิด

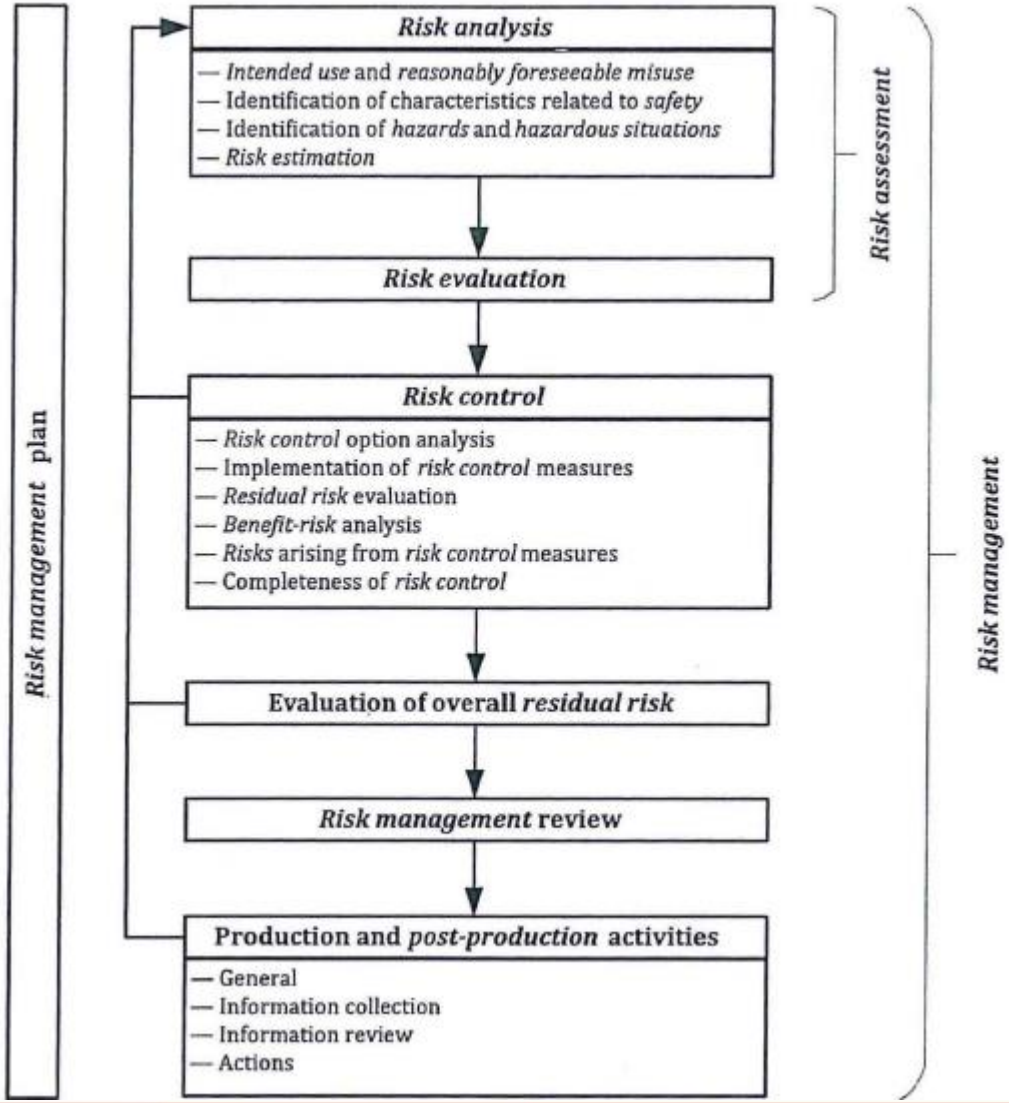
<u>การบาดเจ็บหรืออันตรายแก่ ร่างกาย</u> หรือ ความเสียหายต่อ สุขภาพ ทรัพย์สิน หรือ สิ่งแวดล้อม เช่น ผิวไหม้ ทุลภาพ เสียชีวิต

<u>ระดับความรุนแรง ของอันตราย</u>

เช่น ไม่สะดวก บาดเจ็บ เสียชีวิต

Medical Device Process Standard IEC62304

ISO 14971: 2019 : Software Risk Management Process



Severity

Score	Severity	Possible description
5	Catastrophic	Results in patient death
4	Critical	High chance in permanent impairment or life-threatening Injury
3	Serious	Results in injury or impairment requiring professional medical intervention
2	Minor	Results in temporary injury or impairment not requiring professional medical intervention
1	Negligible	Inconvenience or temporary discomfort

Probability

Score	Frequency	Possible description
3	Weekly	
2	Quarter	
1	Yearly	Occurrence nearly impossible

Ref : *Medical Devices —Application of Risk management to medical devices*, ISO 14971 : 2019.

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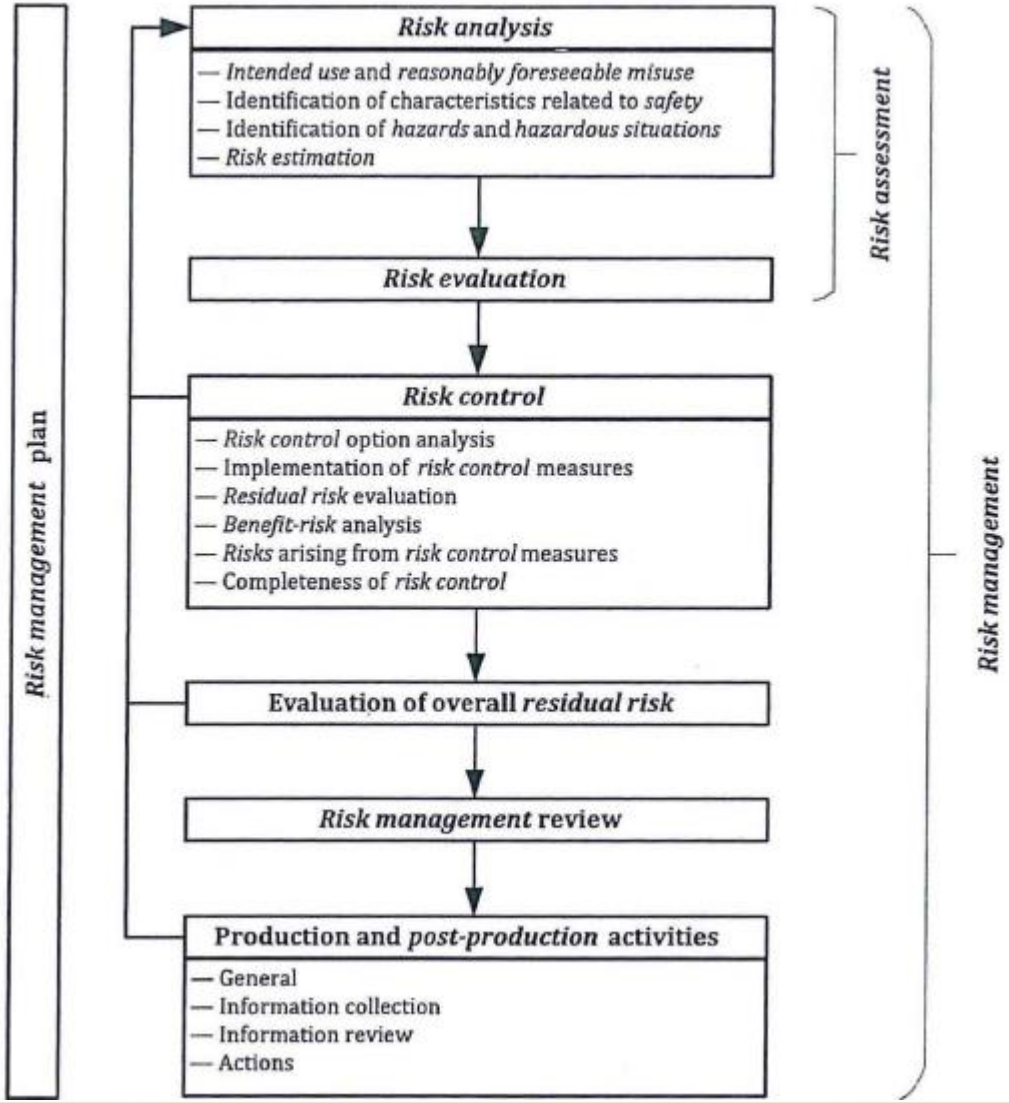
ISO 14971: 2019 : Software Risk Management Process



Risk Level

Severity Category	O- Occurrence		
	3	2	1
5 Catastrophic	15	10	5
4 Critical	12	8	4
3 Serious	9	6	3
2 Minor	6	4	2
1 Negligible	3	2	1

Acceptance Criteria

Risk index	Acceptance Criteria	
1 to 4	Acceptable Area	ACC
5 to 10	As Low as reasonable Possible	ALARP
11 to 20	Not Acceptable Area	NACC

Ref : *Medical Devices —Application of Risk management to medical devices*, ISO 14971 : 2019.

Software Risk Assessment

- ตย. การทำ Software Risk Analysis

Risk Analysis (การวิเคราะห์ความเสี่ยง) — 1

Risk Estimation - Before (การประมาณการความเสี่ยง) + Risk Control — 2

Risk Estimation - After (การประมาณการความเสี่ยง) — 3

6	Risk Analysis (การวิเคราะห์หาความเสี่ยง)						Risk Estimation - Before (การประมาณความเสี่ยง)				Risk Control (มาตรการ / การควบคุมความเสี่ยง เพื่อลดหรือคงความเสี่ยงไว้)	Reference (เอกสารอ้างอิง)	Risk Estimation - After (การประมาณความเสี่ยง)			
7	No.	Product Life Cycle	Hazard/ Sub Hazard (แหล่งกำเนิดของอันตราย)	Foreseeable sequence of events (Potential of failure mode) (แนวโน้มที่จะเกิดอันตราย)	Hazard Situation (Effect of Failure leading to Harm) (ผลกระทบที่จะได้รับ)	Harm อันตราย	Severity	Frequency	Risk Score	Risk evaluation			Severity	Frequency	Risk Score	Risk evaluation
8	1	การออกแบบ	Therapeutic / sofware Item: Pumb Controller :Control function	เกิดเหตุการณ์ที่ไม่มีการตรวจสอบ Over/under dose	Over / under dose	ผู้ป่วยหมดสติ	4	2	8	ALARP	1. เพิ่ม Fun ในการตรวจสอบ Over/under dose	Journal	4	1	4	ACC
9				user use malfunction (3.2) ข้าใจว่ามันเข้า Factory Setting เอง แต่ผู้ใช้ไม่รู้ตัวครับ ดังนั้นค่าที่เหมาะสมกับผู้ใช้ก็จะหายไปด้วย												

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Clause and subclauses \ Class	
4	GENERAL REQUIREMENTS [A,B,C]
4.1	Quality management system
4.2	Risk management
4.3	Software safety classification
4.4	Legacy software
5	SOFTWARE DEVELOPMENT PROCESS
5.1	Software development planning
5.2	Software requirements analysis (SRS)
5.3	Software architectural design
5.4	Software detailed design
5.5	Software unit implementation
5.6	Software integration and integration testing
5.7	Software system testing
5.8	Software release for utilization at a system level

Clause and subclauses \ Class	
6	SOFTWARE MAINTENANCE PROCESS [A,B,C]
6.1	[A, B, C] software maintenance plan
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6.3	Modification implementation
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7.1	Analysis of software contributing to hazardous situations
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7.3	Verification of risk control measures
7.4	**[A, B, C]** Risk management of software changes
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8.1	Configuration identification
8.2	Change control
8.3	[A, B, C] Configuration status accounting

Clause and subclauses \ Class	
9	SOFTWARE PROBLEM RESOLUTION PROCESS [A,B,C]
9.1	Prepares a problem report
9.2	Investigate problem
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IEC 62304 : 2006 + AMD1:2015

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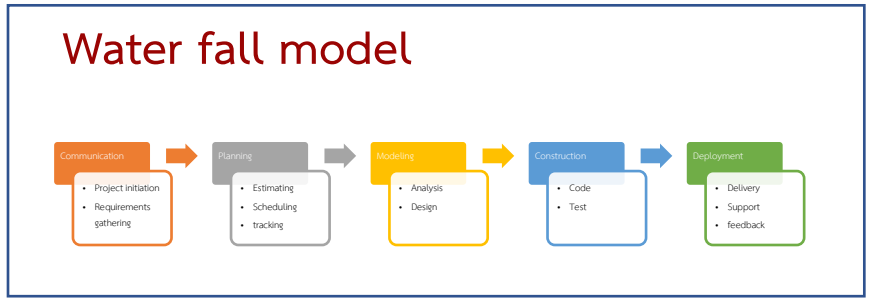
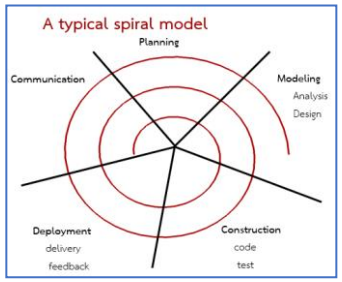
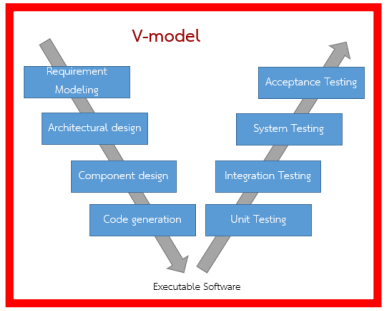
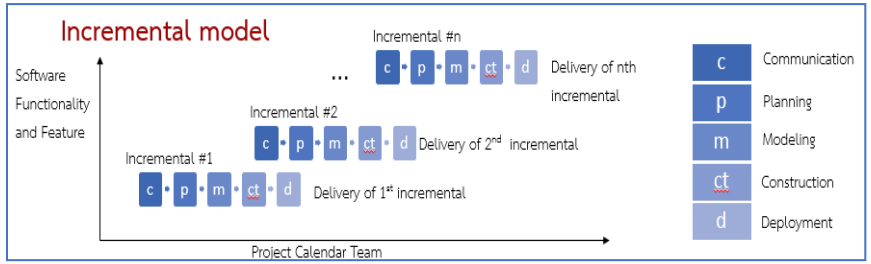
Software Development Life Cycle -SDLC

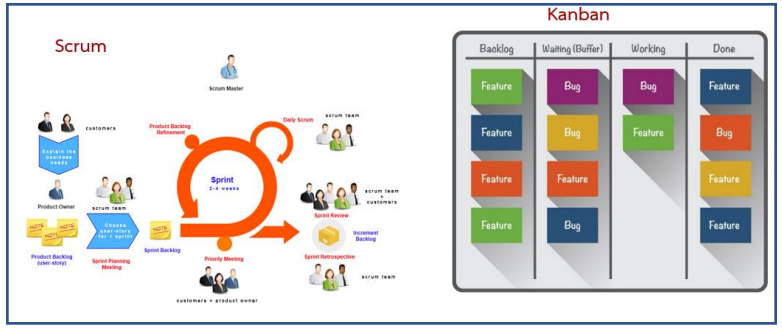








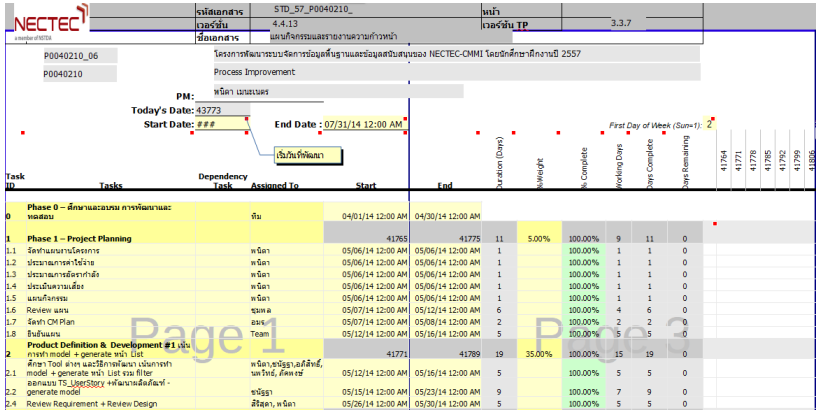
Agile



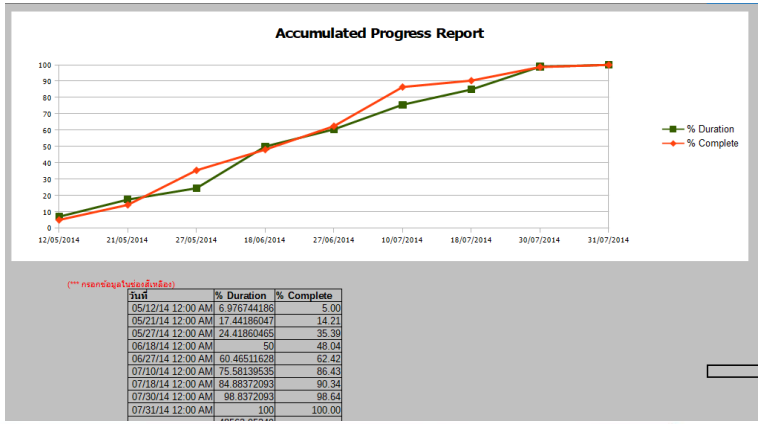
Type of Planning

- Software Integration Planning
- Software Verification Planning
- Risk Management Planning
- Configuration Planning

Software Development Plan



Software Progress Report



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05/21/14 12:00 AM	17.44186047	14.21
05/27/14 12:00 AM	24.41860465	35.39
06/18/14 12:00 AM	50	48.04
06/27/14 12:00 AM	60.46511628	62.42
07/10/14 12:00 AM	75.58139535	86.43
07/18/14 12:00 AM	84.88372093	90.34
07/30/14 12:00 AM	98.8372093	98.64
07/31/14 12:00 AM	100	100.00

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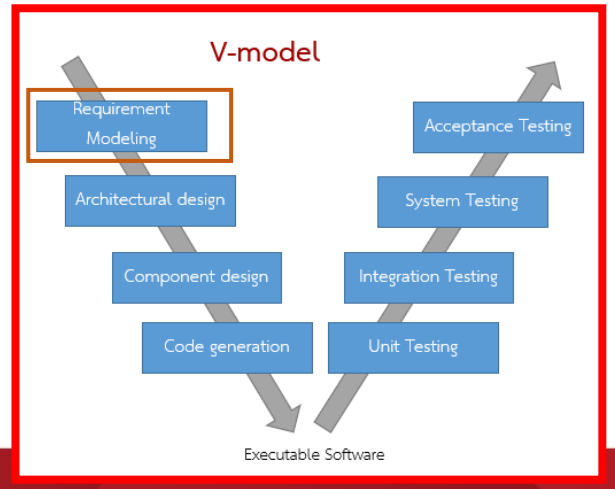

Software Requirement Specification

1. **Introduction**
1.1 Purpose of the requirements document
1.2 Scope of the product
1.3 Definitions, acronyms and abbreviations
1.4 References
1.5 Overview of the remainder of the document
2. **General description**
2.1 Product perspective
2.2 Product functions
2.3 User characteristics
2.4 General constraints
2.5 Assumptions and dependencies
3. **Specific requirements**, covering functional, non-functional and interface requirements. This is obviously the most substantial part of the document but because of the wide variability in organizational practice, it is not appropriate to define a standard structure for this section. The requirements may document external interfaces, describe system functionality and performance, and specify logical database requirements, design constraints, emergent system properties and quality characteristics.

4. **Appendices**

5. **Index:** Although the IEEE standard is not ideal, it contains a great deal of good advice on how to write requirements and how to avoid problems. It is too general to be an organizational standard in its own right. It is a general framework that can be tailored and adapted to define a standard geared to the needs of a particular organization (6).

Figure 1. The SRS structure according the IEEE 830-1998 standard

Ref. Chikh, A., & AlAjmi, H.H. (2014). Towards a dynamic software requirements specification. *2014 World Congress on Computer Applications and Information Systems (WCCAIS)*, 1-7.

Traceability Metrix

BRD- Section	FSD- Section	Test scenario ID	Test case ID	Status	Defects
1- Loan Process	1.1- New users	TS_Loan_001- Validate the "Apply Loan" feature as a new user	TC_newuser_01	Passed	
			TC_newuser_02	Passed	
			TC_newuser_03	Failed	Defect_01, Defect_02
		TS_Loan_002- validate the "Apply Loan" feature as a already existing user	TC_newuser_04	Passed	
			TC_newuser_05	Blocked	Defect_01
			TC_newuser_06	Failed	Defect_03
			TC_newuser_07	Passed	
		TS_Loan_003- For a new user in the "Apply loan", check the guest customer option and apply loan	TC_newuser_08	Passed	
		TS_Loan_004 - For a new user in the "Apply loan", check the Register option and apply loan	TC_newuser_09	Passed	
	1.2- Existing users	TS_Loan_005- Login to the loan portal as an already a customer with a loan and check the information displayed	TC_Exist_User_01	Passed	
		TS_Loan_006-Check the Loan whose status is "Sent for review"	TC_Exist_User_02	Passed	
		TS_Loan_007-Check the Loan whose status is "Reviewed and Accepted"	TC_Exist_User_03	Passed	
		TS_Loan_008-Check the Loan whose status is "Reviewed and deleted"	TC_Exist_User_04	Passed	
2- Ease of use	2.1- Ease os use	TS_Loan_009-Check for a visitor if the information on the site is accessible in less than 3 clicks or not	TC_EasyUse_01	Passed	
		TS_Loan_010-Check for a registered user if the information on the site is accessible in less than 3 clicks or not	TC_EasyUse_02	Passed	
		TS_Loan_011-Check for a banker if the information on the site is accessible in less than 3 clicks or not	TC_EasyUse_03	Passed	

Ref: https://www.softwaretestinghelp.com/requirements-traceability-matrix/

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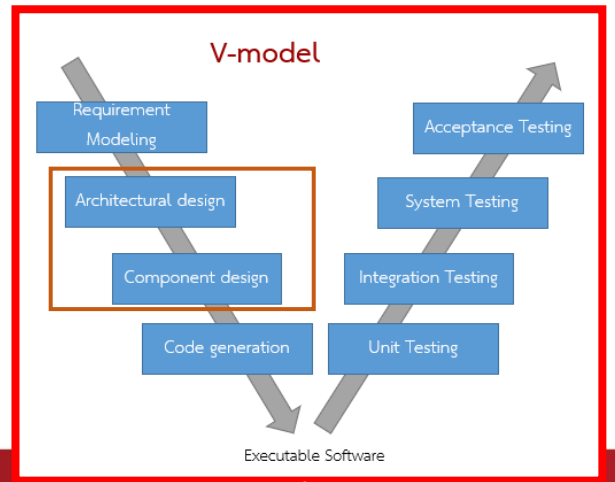
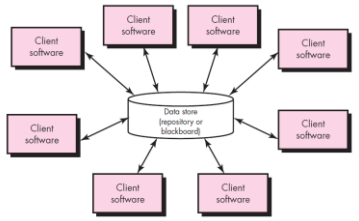
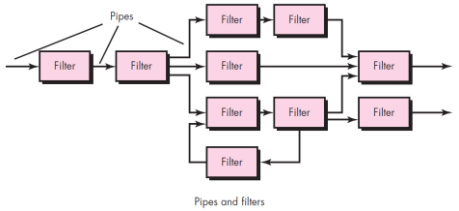


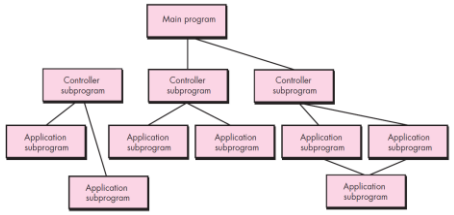
Architectural Styles



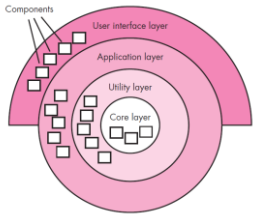
Data center Architectural



Data Flow Architectural

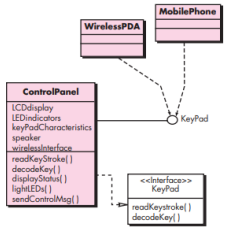


Main program / sub main program Architectural

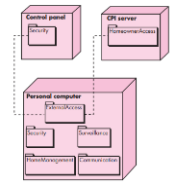


Layer Architectural

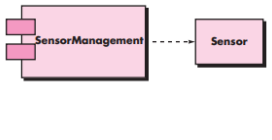
Software design



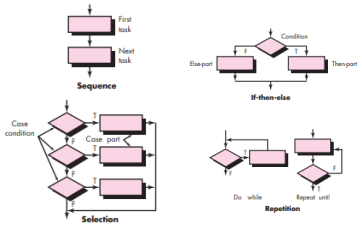
Interface Design



Deployment Level Design

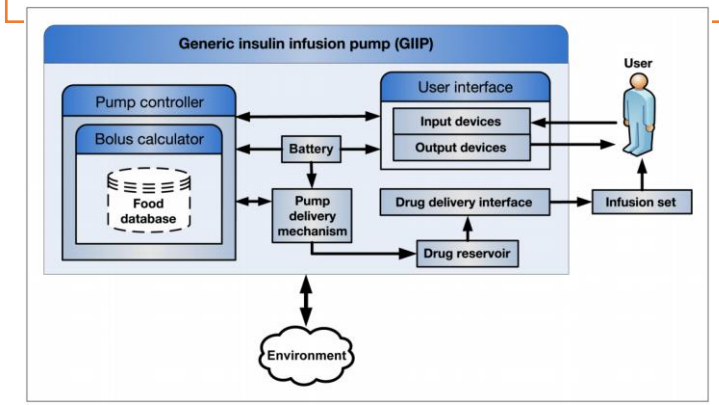


Component Level Design

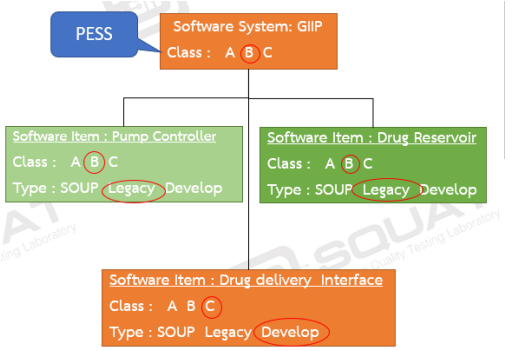


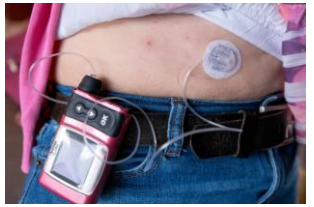
Flow Chart

Case study: Generic insulin infusion pump



System architecture of generic insulin infusion pump (GIIP)





Pic Ref: https://www.cbc.ca/news/health/implant-files-insulin-pumps-1.4915491

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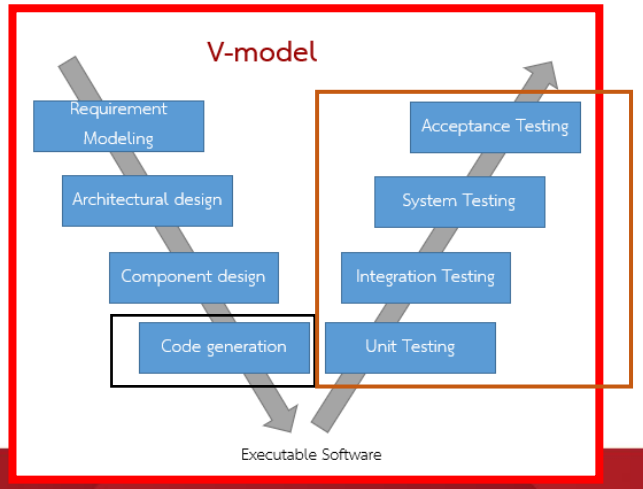
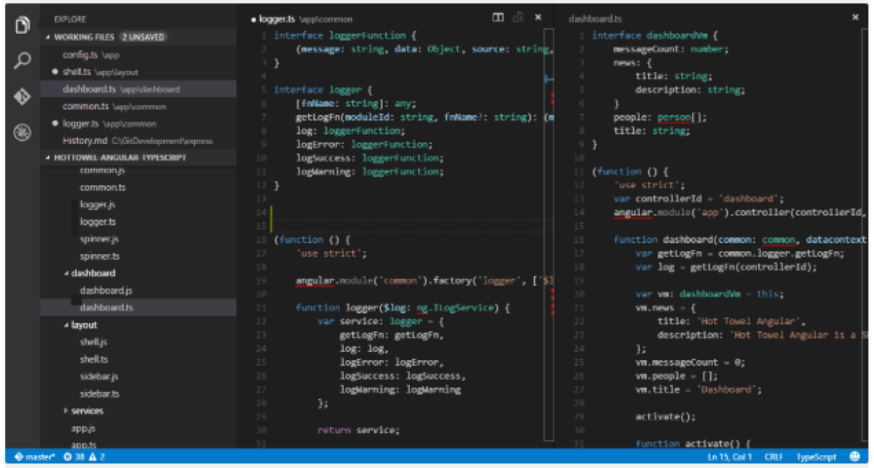
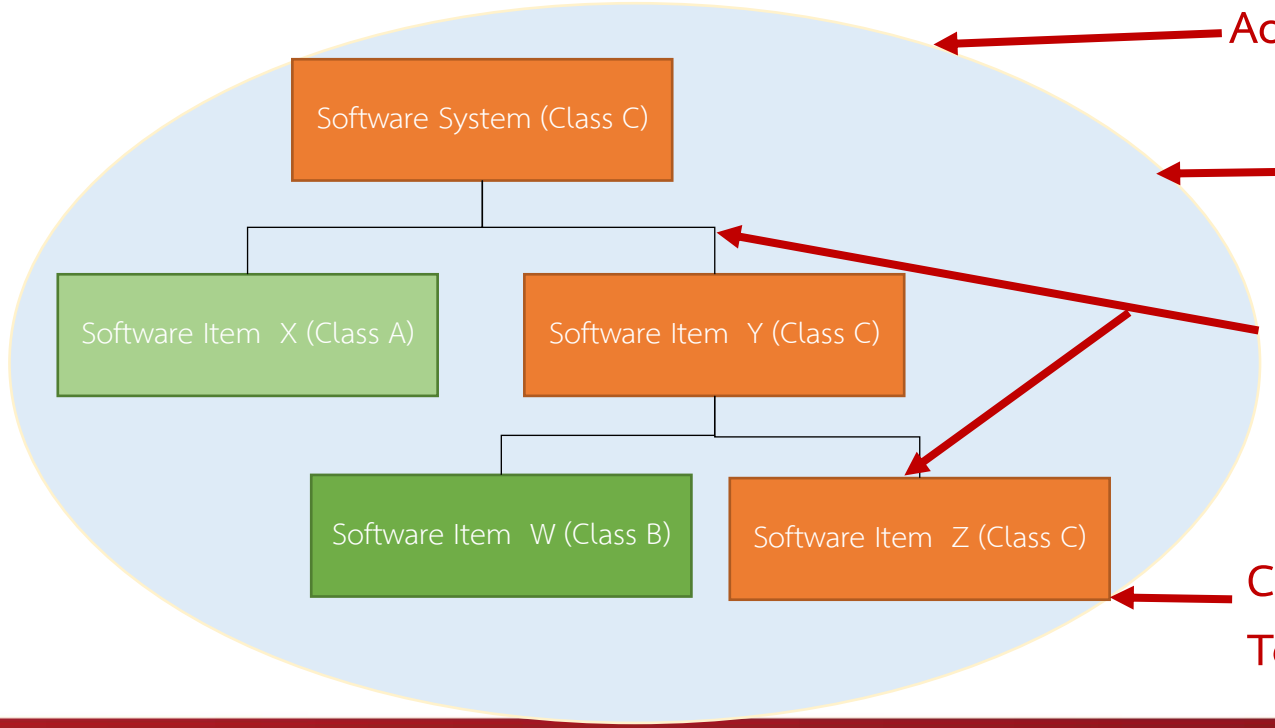




Software unit implementation

Test levels are groups of test activities that are organized and managed together. Each test level is an instance of the test process.



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: Software Configuration Management

Software Configuration Items e.g.

Phases/Activities	Output	CI	Tool/Control Method	Responsible	Reviewer	Approver
Planning	Project Planning	☞	Store in	Project Manager	System Engineering Team	Supervisor
Requirement Analysis	Requirement and Risk Documents	✓		Project Manager	System Engineering Team	Clients
Design	Design Documents	✓		Project Manager	System Engineering Team	Supervisor
Implement	Source Code	✓	GitLab	Developer	System	Project

Versioning

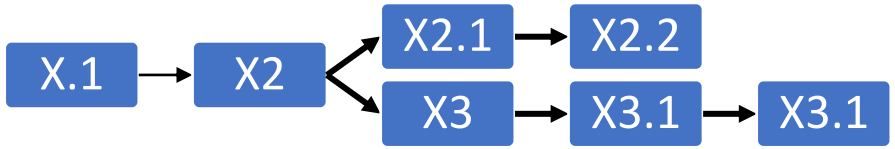
Naming convention

สำหรับแบบฟอร์ม มีหลักการตั้งชื่อเอกสารมาตรฐานมีรูปแบบดังนี้

F-ลำดับเอกสาร –ชื่อเอกสารภาษาอังกฤษ

โดย ชื่อเอกสารภาษาอังกฤษ จะต้องใช้ชื่อที่สื่อความหมายเหมาะสมกับเนื้อหา ซึ่งตัวอักษรแรกของคำเป็นตัวพิมพ์ใหญ่เสมอ ยกเว้นเป็นคำบุพบทหรือคำเชื่อม เช่น **F-001-SoftwareDevelopmentPlan** แบบฟอร์มแผนการพัฒนาซอฟต์แวร์ ตั้งชื่อไฟล์เป็น xxx-SoftwareDevelopmentPlan

Development Path



- Commit
- Check in
- Check out
- merge

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8.3	[A, B, C] Configuration status accounting

Clause and subclauses \ Class	
9	SOFTWARE PROBLEM RESOLUTION PROCESS [A,B,C]
9.1	Prepares a problem report
9.2	Investigate problem
9.3	Advises relevant parties
9.4	Use change control process
9.5	Maintains records
9.6	Analyze problem for trends
9.7	Verify problem resolutions
9.8	Test documentation content

IEC 62304 : 2006 + AMD1:2015

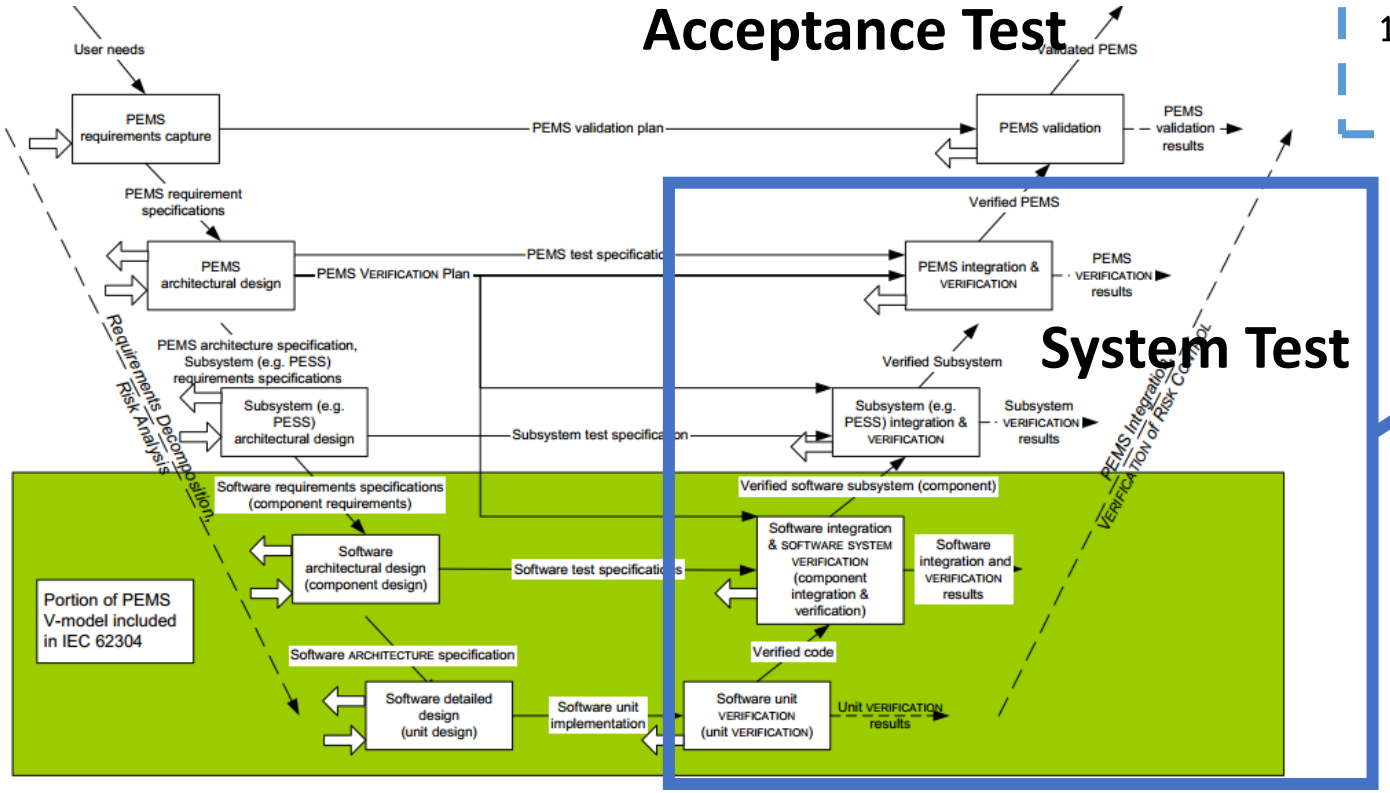
Medical Device Process Standard IEC62304

Development

Release

Acceptance Test

System Test



6. SOFTWARE MAINTENANCE PROCESS

Feedback Report

Defect / Problem ?

No

Yes

1. Inform customer
2. Enhancement

9. SOFTWARE PROBLEM RESOLUTION PROCESS

Evaluate / Re-assess risk (7.)

HW / SW ?
Infra ? Safety?

Need Change ?

No

Yes

Workaround

Change Management Process
(8.2 Change Control)
Record change request

5. SOFTWARE DEVELOPMENT PROCESS

Medical Device Process Standard IEC62304

Example: IEC62034 Test Report - The Evidence List

TABLE: Mapping of required evidence and manufacturer documents				
Standard Clause	Deliverables	Title	Revision #	Date
4.2	Risk management file	P001_RiskManagementFile	1.0	20/07/2020
4.3	Software safety classification document			
4.3	Specification of risk control measures external to software system			
4.3	Rationale of classification for decomposed software system			
4.4.2	Risk management activities for legacy software			
4.4.3	Gap analysis for legacy software			
4.4.4	Gap closure plan for legacy software			
4.4.5	Rationale for use of legacy software			
5.1.1	Software development plan			

File name

Baseline/ publish revision

Baseline/ publish/ approve Date

Case Study

Evidence List

TABLE: Mapping of required evidence and manufacturer documents				
Standard Clause	Deliverables	Title	Revision #	Date
4.2	Risk management file	F-PASS-030-RiskMngmnt	Version 3.0	8/12/2020
4.3	Software safety classification document	F-PASS-030-RiskMngmnt : 4	Version 3.0	8/12/2020
4.3	Specification of risk control measures external to software system	F-PASS-030-RiskMngmnt : 7.5	Version 3.0	8/12/2020
4.3	Rationale of classification for decomposed software system	F-PASS-030-RiskMngmnt :	Version 3.0	8/12/2020
4.4.2	Risk management activities for legacy software	F-PASS-030-RiskMngmnt : 9	Version 3.0	8/12/2020
4.4.3	Gap analysis for legacy software	F-PASS-030-RiskMngmnt : 9	Version 3.0	8/12/2020
4.4.4	Gap closure plan for legacy software	F-PASS-030-RiskMngmnt : 9	Version 3.0	8/12/2020
4.4.5	Rationale for use of legacy software	F-PASS-030-RiskMngmnt : 9	Version 3.0	8/12/2020
5.1.1	Software development plan	F-PASS-030-DevPlan : 4.1	Version 3.0	8/12/2020
5.1.3	Software requirements reference to software design and development document	N/A	N/A	N/A

Photo Documentation

Test Item: R63-013-IT04-01
MD5 (R63-013-IT04-01.zip) = 509c7de497efa7b0d5e2d6f3b458374b

Detail of:	List of software developments Version 1.0
	

Example: IEC62034 Test Report

Job No.	J64-001	Report Reference No.	J64-001-TR01
Applicant's Name	Neural Signal Processing Research Team (NSP) , NECTEC		
Product	PASS Pro-version		

TEST REPORT
IEC 62304
Medical device software
Software life-cycle processes

Report Number.	J64-001-TR01
Date of issue	30 December 2020
Total number of pages	35
Name of Testing Laboratory preparing the Report	SEPT/NECTEC
Applicant's name	Neural Signal Processing Research Team (NSP) , NECTEC
Address	NECTEC 112 Thailand Science Park, Khlong Nueng, Klong Luang, Pathumthani 12120
Test specification:	
Standard	IEC 62304:2006 (First Edition) + A1:2015 (or IEC 62304:2015 CSV)
Test procedure	NECTEC Testing Report
Non-standard test method	N/A
Test Report Form No.	FM-TR-04
Test Report Form(s) Originator	SEPT/NECTEC
Master TRF	3.0

This report is not valid as a CB Test Report unless signed by an approved NECTEC Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

General disclaimer:

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Form Code: FM-TR-04 Page 1 of 35
Form version: 3.0 Publish Date: 21/08/63

Example: IEC60601-1 Cl.14 Test Report

Job No.	J64-001	Report Reference No.	J64-001-TR02
Applicant's name	Neural Signal Processing Research Team (NSP) , NECTEC		
Product	PASS Pro-version		

TEST REPORT
IEC 60601-1 only Clause 14
Medical electrical equipment
Part 1: General requirements for basic safety and essential performance

Report Reference No.	J64-001-TR02
Date of issue	30 December 2020
Total number of pages	11
Name of Testing Laboratory preparing the Report	SEPT/NECTEC
Applicant's name	Neural Signal Processing Research Team (NSP), NECTEC
Address	NECTEC 112 Thailand Science Park, Khlong Nueng, Klong Luang, Pathumthani 12120
Test specification:	
Standard	IEC 60601-1:2005 (Third Edition) + CORR.1:2006 + CORR.2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint)
Test procedure	NECTEC Testing Lab
Non-standard test method	
Test Report Form No.	FM-TR-05
Test Report Form Originator	SEPT/NECTEC
Master TRF	3.0

This report is not valid as a CB Test Report unless signed by an approved NECTEC Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

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Form Code: FM-TR-05 Page 1 of 11
Form Version: 3.0 Publish Date: 21/08/63

ข้อกำหนดที่ไม่สอดคล้องกับมาตรฐานที่พบบ่อย

IEC 62304		
Clause	Requirement + Test	Class
4	GENERAL REQUIREMENTS	
4.1	[A, B, C] Quality management system	A
4.2	[A, B, C] Risk management	A
4.3	[A, B, C] Software safety classification	A
4.4	[A, B, C] Legacy software	A

4.1 ส่วนใหญ่ผิดที่ไม่ได้ถาม อ.ย. ก่อน ว่าเป็น medical device ประเภทไหน

4.2 ส่วนใหญ่มี Risk management file ตาม ISO 14971
ถ้า Fail คือ ไม่มี Risk management file ตาม ISO 14971

4.3 ถ้า Fail คือ ไม่มี การทำ System Architecture และ ไม่ประเมิน Software Safety classification

4.4 ถ้า Fail คือ ส่วนใหญ่ไม่มีการแสดงผลการวิเคราะห์

- ในแต่ละ Software Item เป็น Legacy, SOUP, develop
- ไม่มีขั้นตอนและผล การประเมินความเสี่ยงของ Legacy ใน Risk Assessment
- ไม่มีขั้นตอนการจัดการ Legacy ใน Deliverables without performing activities required by
  - 5.2 (Requirement analysis)
  - 5.3 (Architectural design)
  - 5.7 (System Testing)
  - and Clause 7 (Risk management)

ข้อกำหนดที่ไม่สอดคล้องกับมาตรฐานที่พบบ่อย

IEC 62304		
Clause	Requirement + Test	Class
5	SOFTWARE DEVELOPMENT PROCESS	A
5.1	Software development planning	A
5.2	Software requirements analysis (SRS system description/external interface requirements/ functional req/performance req/safety req/ design constrain)	
5.3	Software architectural design	
5.4	Software detailed design	B
5.5	Software unit implementation	A
5.6	Software integration and integration testing	
5.7	Software system testing	
5.8	Software release for utilization at a system level	

5.1 ส่วนใหญ่ผิดที่ Software development plan

- ไม่อธิบายขั้นตอนและการเชื่อมโยงเอกสารไปยังกระบวนการอื่นๆ ตาม IEC62304 Cl. 6 – 9
- ไม่มีการกำหนด deliverable
- ไม่มีหลักฐานการทำ Tracebility Metrix
- ไม่มีการกำหนด CI ทั้งของ SOUP, Legacy, develop
- ไม่มีการแสดงหลักฐานผลของ Appropriate plan

5.2 ส่วนใหญ่ผิดที่ Software requirement specification – SRS

- ไม่มีผลการวิเคราะห์ 5.2.2 requirements a) – l)
- ไม่มีผลการ re-evaluates the medical device risk analysis when software requirements are established and update it as appropriate
- ไม่มีผลการ verify 5.2.6 requirements a) – f)

5.3 และ 5.4 ไม่ได้ require ต้องทำใน Software safety classification A

แต่ขอให้ทำ System Architecture

- เพื่อนำไปประเมิน Software Safety classification และ Risk assessment

ข้อกำหนดที่ไม่สอดคล้องกับมาตรฐานที่พบบ่อย

5.5 ไม่ได้แสดงหลักฐานการทำ Software Unit implementation เช่น ที่จัดเก็บ Source code, Executable code

5.7 ส่วนใหญ่ผิดที่เอกสารการทดสอบ Software system testing

- ไม่ระบุ a set of tests, expressed as input stimuli, expected outcomes, pass/fail criteria and procedures
- ไม่ระบุและไม่ verify strategies and test procedures
- When changes are made during software system testing, the manufacturer: repeated tests (repeatability), perform modified tests, performs relevant risk management activities as defined in 7.4
- repeatability of tests 5.7.5 a) – g)

5.8 Software release for utilization at a system level

- ขาดผลการแสดง residual anomalies
- ไม่ระบุ version of the medical device software ที่ released
- establishes procedures to ensure that the released medical device software
  - replication, media labelling, packaging, protection, storage, delivery

ข้อกำหนดที่ไม่สอดคล้องกับมาตรฐานที่พบบ่อย

IEC 62304		
Clause	Requirement + Test	Class
6	SOFTWARE MAINTENANCE PROCESS	
6.1	[A, B, C] The manufacturer establishes a software maintenance plan (or plans) for conducting the activities and tasks of the maintenance process	A
6.2	Problem and modification analysis	
6.3	Modification implementation	
6.3.1	[A, B, C] The manufacturer identifies and perform any Clause 5 activities that need to be repeated as a result of the modification	A
6.3.2	[A, B, C] The manufacturer releases modifications according to 5.8	A

ส่วนใหญ่ผิดที่ ไม่มีกระบวนการ 6.1 – 6.3 และ ผลการใช้กระบวนการ (Pilot)

IEC 62304		
Clause	Requirement + Test	Class
7	SOFTWARE RISK MANAGEMENT PROCESS	
7.1	Analysis of software contributing to hazardous situations	
7.2	Risk control measures	
7.3	Verification of risk control measures	
7.4	Risk management of software changes	
7.4.1	[A, B, C] The manufacturer analyses changes to the medical device software (including soup) to determine whether:	A
	a) additional potential causes are introduced contributing to a hazardous situation	A
	b) additional software risk control measures are required	A
7.4.2	[B, C] The manufacturer analyses changes to the software, including changes to soup, to determine whether the software modification could interfere with existing risk control measures	B
7.4.3	[B, C] The manufacturer performs relevant risk management activities defined in 7.1, 7.2 and 7.3 based on these analyses	B

- ไม่มี การทำ System Architecture และ ไม่มีการประเมิน PESS / Software Item ใน Risk management file ตาม ISO 14971
- ไม่มีการ reevaluate risk assessment กรณี Change

ข้อกำหนดที่ไม่สอดคล้องกับมาตรฐานที่พบบ่อย

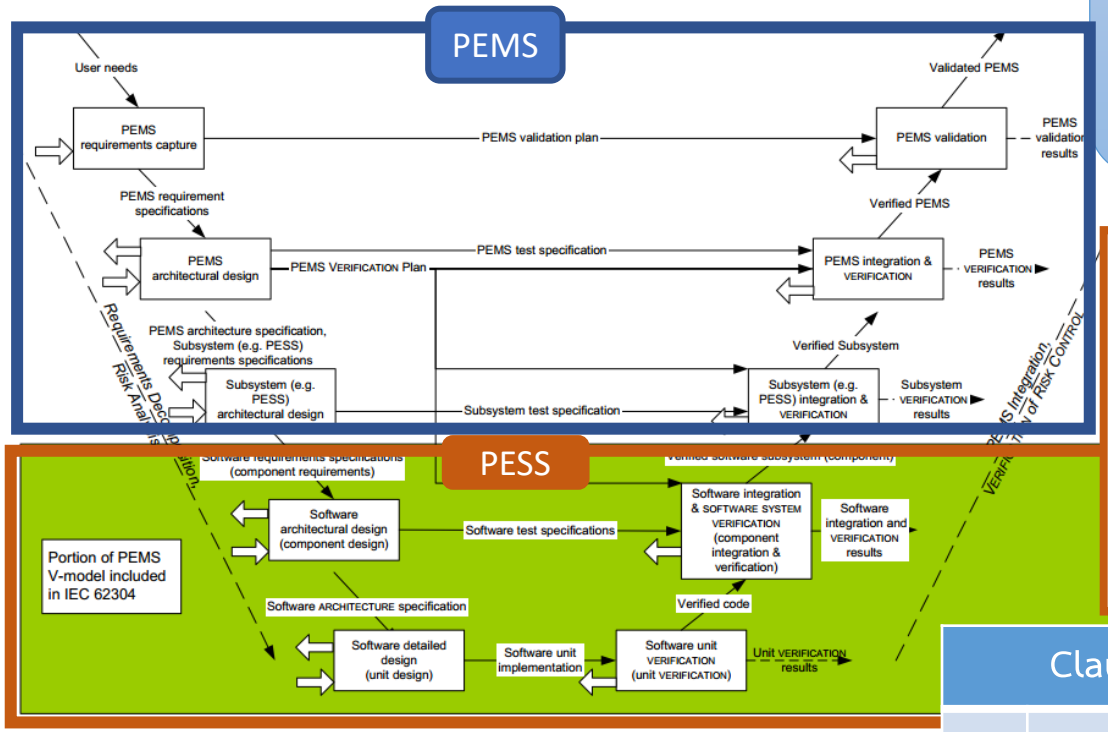
IEC 62304		
Clause	Requirement + Test	Class
8	SOFTWARE CONFIGURATION MANAGEMENT PROCESS	
8.1	Configuration identification	
8.2	Change control	
8.3	[A, B, C] The manufacturer retains retrievable records of the history of controlled configuration items including system configuration	A

- ไม่มีการระบุ CI
- ไม่มีการอธิบายขั้นตอนและแสดงบันทึกของ Change Control

IEC 62304		
Clause	Requirement + Test	Class
9	SOFTWARE PROBLEM RESOLUTION PROCESS	
9.1	[A, B, C] The manufacturer prepares a problem report for each problem detected in the medical device software	A
9.2	[A, B, C] The manufacturer:	
9.3	[A, B, C] The manufacturer advises relevant parties of the existence of the problem, as appropriate	A
9.4	[A, B, C] The manufacturer approves and implements all change requests, observing the requirements of the change control process	A
9.5	[A, B, C] The manufacturer maintains records of problem reports and their resolution including their verification	A
	The manufacturer updates the risk management file as appropriate	A
9.6	[A, B, C] The manufacturer performs analysis to detect trends in problem reports	A
9.7	[A, B, C] The manufacturer verifies resolutions to determine whether:	A
9.8	[A, B, C] When testing, retesting or regression testing software items and systems following a change, the manufacturer includes in the test documentation:	A
	a) test results	A
	b) anomalies found	A
	c) the version of software tested	A
	d) relevant hardware and software test configurations	A
	e) relevant test tools	A
	f) date tested	A
	g) identification of the tester	A

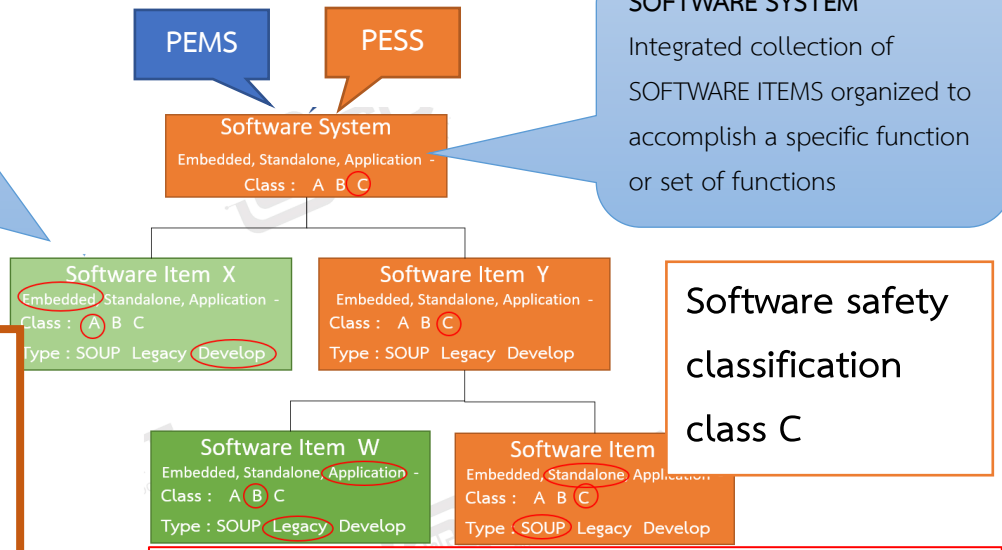
- ไม่มีการอธิบายขั้นตอนและแสดงบันทึกของ Software problem resolution
- ไม่มีการผลการทดสอบเมื่อเกิดการ Change (9.8)

Summary



SOFTWARE ITEM
Any identifiable part of a computer program, i.e., source code, object code, control code, control data, or a collection of these items

SOFTWARE SYSTEM
Integrated collection of SOFTWARE ITEMS organized to accomplish a specific function or set of functions



Standards for software medical device

IEC 60601-1 : 2005 + AMD1:2012 Cl.14

IEC 62304 : 2006 + AMD1:2015

Software safety classification class C

- Terminology
  - Software, PEMS, PESS, Software Item, SOUP, Legacy
  - SDLC – V Model
  - Architecture, software safety classification
  - IEC 62304: 2006 + AMD1:2015 requirements

Clause and subclauses \ Class	
4	GENERAL REQUIREMENTS [A,B,C]
5	SOFTWARE DEVELOPMENT PROCESS
6	SOFTWARE MAINTENANCE PROCESS [A,B,C]
7	SOFTWARE RISK MANAGEMENT PROCESS
8	SOFTWARE CONFIGURATION MANAGEMENT PROCESS [A,B,C]
9	SOFTWARE PROBLEM RESOLUTION PROCESS [A,B,C]

- **Legacy Software**

MEDICAL DEVICE SOFTWARE which was legally **places on the market and is still market today** but for which there is insufficient objective evidence that it was developed in compliance with the current version of this standard.

- **Software of unknown provenance – SOUP**

SOFTWARE ITEM that is already developed and generally available and that has not been developed for purpose of being incorporated into the MEDICAL DEVICE **[off – the – self software] or** SOFTWARE ITEM previously developed for which adequate records of the develop PROCESSES are not available.

Q & A

อ้างอิง (Reference)

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- Ivan Mistrik, Richard M. Soley, Nour Ali, John Grundy, and Bedir Tekinerdogan. 2015. Software Quality Assurance: In Large Scale and Complex Software-Intensive Systems (1st ed.). Morgan Kaufmann Publishers Inc., San Francisco, CA, USA.
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- *Medical Device Software—Software Life Cycle Processes*, ANSI/AAMI/IEC 62304 : 2006 + AMD : 2015.
- *Medical electrical equipment—Part1 General Requirement for basic safety and essential performance*, IEC 60601-1 : 2005 + AMD1: 2012

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