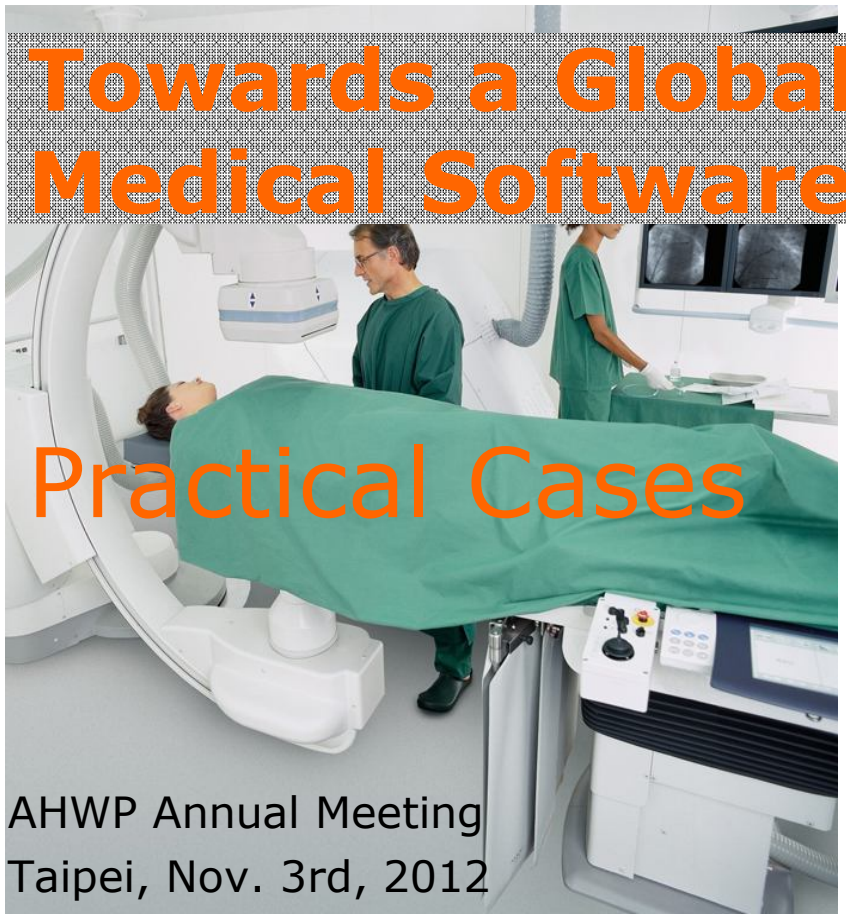
COCIR

Sustainable Competence
in Advancing Healthcare

Towards a Global Vision on Medical Software



Practical Cases

AHWP Annual Meeting
Taipei, Nov. 3rd, 2012

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Today's views differ globally

- All Software in a hospital should be qualified as a medical device?
- All Software in a hospital should be developed according to MD specific product standards?
- Only Software which is actively involved in the diagnoses and treatment, thus an essential part of such, should be developed according to MD product standards and qualify as a medical device?

All stakeholders however agree Software used in a healthcare domain must be safe according to its intended use and risk-benefit assessment.

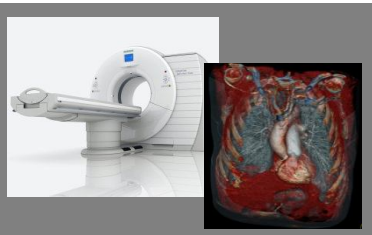
Changing Environment: from Product to Process

	(Hardware) Modality - Device & Regulation -	H IT - Market & Industry -
Vendor	**Single vendor** focus on a device …with standard interfaces	**Multi vendor** and multi product environment with strong responsibility of provider
Technology		
Process		
Users		
Customization		
Safety focus		

Product Process

Software as Medical Device (standalone)

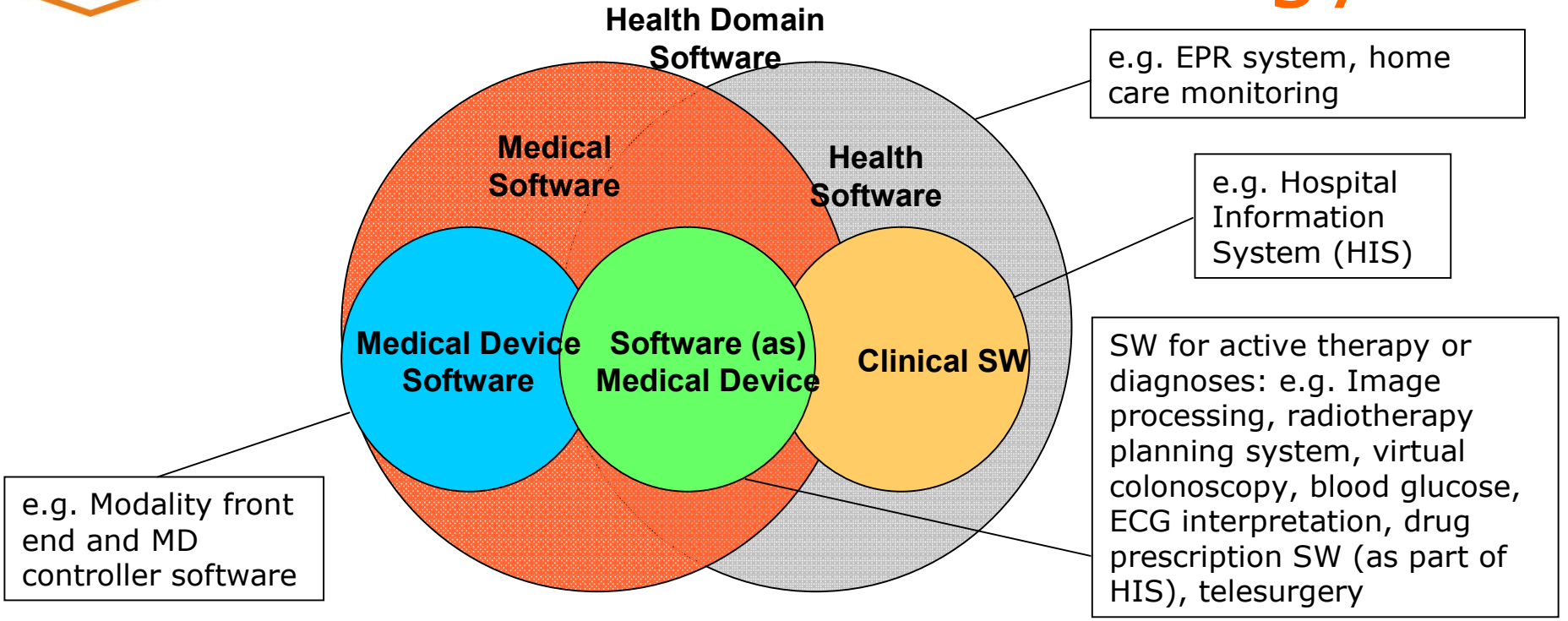
- Not: Software, which are embedded in MD, i.e. one does not achieve its intended use without the other
  - System-view (HW + SW)



- Software-”only” Products – what is different?
  - … available on CD / DVD or download
  - Functioning is in-dependent from a HW MD, or modalities such as MRI, CT …
  - … can function on any “general purpose” PC, which fulfils the requirements of the Medical-Software-Manufacturer – the HW is NOT part of the medical device!

Image viewer, diagnosis and archiving software

Overview Health Domain Software terminology



Health Software Domain
All kind of Software specifically developed for the purpose of being incorporated into a health environment.
Health software
Software developed specifically for the purpose for maintaining and improving health of individual persons.
Medical Software
Software developed for the purpose of being incorporated into a medical device or intended to be a Medical Device in its own right.
Medical Device Software
Medical Software specifically developed for the purpose of being incorporated (embedded) into a Medical Device.
Software (as) Medical Device
Medical or Health Software intended to be a Medical Device in its own right (stand alone).
Clinical Software
Health Software specifically developed for the purpose of being incorporated into a clinical environment.

Software MD in the hospital domain

Example software "only" medical devices

(acc. intended use def. by manufacturer)

- **Picture Archiving and Communication System (PACS)**
- Hospital Information System (HIS) incl. prescription module
- **Radiological Information System (RIS)**
- Decision Support System
  - Radiotherapy Planning System
  - Computer Aided Diagnosis

Clinical Use: Reporting / Diagnoses on radiological images
(left to right):
Radiology Information System (RIS),
Image Picture and Archiving System (PACS),
Postprocessing Software

Different classification of PACS acc. to MDD

class	Description
class I	PACS Archiving & Retrieval (without image of „In Vivo Distribution of tracer" (PET, NM) (MDD, Annex IX, rule 1+12)
class I*	Workplaces *without* image of "In Vivo Distribution of tracer" (PET, NM) incl. measuring functions, e.g. distances, angles,.... (MDD, Annex IX, rule 1+12; Annex VII)
class IIa	Workplaces with complete DICOM connectivity, (incl. measuring functions) *including* image of "In Vivo Distribution of tracer" (PET, NM) (MDD, Annex IX, rule 10)
class IIb	Medical Workstation (incl. measuring functions) "control … or directly influence … a device intended for diagnostic radiology … " (MDD, Annex IX, II 2.3, rule 10)

Different PACS/RIS Classification globally (examples*)

Canadian Medical Device Regulation:
- QMS (ISO 13485:2003) for class II - IV devices
- Registration
- Product Licences cl. II / III
  - PACS = class II
  - RIS = class I

China,
- Product Licences based on approval of „Country of Origin“ = Europ. CE
  - PACS = class II
  - RIS = not specified
- Guidances, Ordinances

U.S. FDA 21CFR820
Quality System Regulation:
- QMS („Good Manufacturing Practises“)
- Product specific guidances (e.g. PACS)
- Registration
- Product Approvals:
  - PACS = class II (moderate level of concern)
  - RIS = not yet regulated, but: new guidance „MDDS“ in preparation

Directive 93/42/EEC Medical Devices +
Medical Devices regulations in member states
- QMS (ISO 13485) > cl.I devices mandatory
- Registration of MFR / Authorized Rep.
- Conformity Assessment:
  - PACS = cl. I, IIa, IIb
  - RIS = none or cl. I

Therapeutic Goods Act
- Registration Manufacturer
- Conformity Assessment – EU CE is pre-requisite for Australian DoC:
  - PACS = class II
  - RIS = class I

** Selected countries only*

Examples for Software not being a MD

- Software platform without medical purpose, used as an integral part of another medical device (like e.g. firmware).
- Software gateways connecting medical and non-medical software.
- Finished Device Software without medical purpose, e.g. for administration (billing system), even if used in medical environment.
- General IT software (MS windows, etc.) not considered a medical device, but regulated under different laws.

Peculiarity of SW: Modification

- Medical Software enables customised modifications and continuous updates (incl. hotfix) all necessary to address customer needs. This can be done rapidly (code change, validation) and remotely.

- All modifications shall be managed according to the specified change process.

- Maintenance/repair or update activities for already marketed devices usually do not incorporate changes that influence the conformity of the device.

- On the other hand upgrades (e.g. adding of new functionality) might result in a change of the intended use und such will require a new Conformity Assessment and Declaration of Conformity.

Peculiarity of SW: Testing

- Traditional testing/assessment of MD not adequate to address the safety of a MD based on software in full or in part.

- Assessment requires that a process based on risk management and the use of a development methodology (software life-cycle concept) is followed for the design of the software and that records of that process are established to support the safety of the medical device.

- Therefore, a pure product related evaluation without consideration of the design process is not considered adequate.

Modifications and Testing of Software

Situation in selected regulatory regimes for 1. Testing & 2. Modifications

Europe

1. Authorities do not need to test stand alone SW, i.e. manufacturer perform tests under its own responsibility and use MD specific standards.

2. Generally, SW modifications do not require a re-registration/re-licensing in the EU, if the primary intended use remains unchanged.

China

1. Tests to be performed by manufacturers and test institutes (Type testing institutes uses standards (GB25000.51) which are not MD specific

2. Modifications handled like new products, no distinction between significant and non-significant changes

USA

1. Tests to be performed by manufacturers and test institutes

2. Not require new clearance, if the modifications are identified "minor" according to SW Modification guidance

Conclusions

- Software as Medical Device (stand alone) has different characteristics and mode of operation compared to traditional hardware devices.

- Safety first in any case – but approach is different thus proper qualification and classification of S/W MD crucial. MD Software specific standards can help.

- Updates do not change the intended use and should be covered under the original conformity assessment.

- Globally coordinated approach needed giving manufacturers clear market access conditions.

Thank you for

your attention.

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