– Medical Software 3 –

Medical software guidance and recent update in Japan

2014 Nov. 19th
in AHC and AHWP Joint Workshop

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Who are DITTA and JIRA?

- DITTA is a global organization representing Industry Associations of Manufacturers around the world.
- DITTA was officially incorporated in 2012 as a non-profit trade association in the United States after more than 12 years of existence.
- JIRA is a Japan Medical Imaging and Radiological Systems Industries Association.
- JIRA is major member in DITTA, and JIRA is Co Coalition Leader of Medial Device Coalition in APEC RHSC as major Japanese Industry Association.

DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

Chair 2011-2012
US NEMA-MITA

Chair 2013-2014
EU COCIR

Chair 2015-2016
Japan JIRA

Summary of PAL revision

- Points of the amendment are to;
  1. Strengthen safety measures regarding drugs and medical devices
  2. Revise medical device regulations based on its characteristics
  3. Introduce Regenerative and Cellular Therapy Products (RCTP) & Gene Therapy Products (GTP) regulations based on their characteristics
- Name of PAL will be changed to “Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics” (, called “PMD Act”).
- The chapter for “Medical Device” will be prepared.

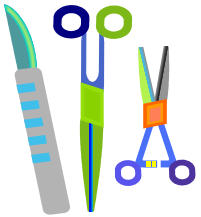
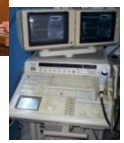
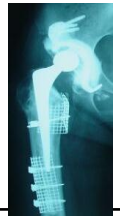
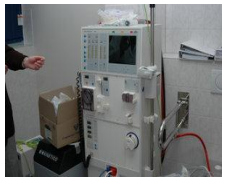
For implementation of PMD Act:

- Revision of Pharmaceutical Affairs Law (PAL) was adopted by the Diet, and announced on 27 November 2013.
- Medical Device Development Promotion Act was announced on 27 June 2014.
- Relevant cabinet and ministerial ordinances as well as notifications were issued in July and August 2014.
- The amendment law is to be enforced on 25 November 2014.
- More details will be notified subsequently.

Points of PMD Act

1. Regulatory Requirements for medical device marketing/manufacturing business in a different chapter from the chapter for drugs
2. Extend the application of the third party certification system for medical devices using the private certification bodies to Class III medical devices by specifying the standards
3. Stand-alone diagnostic software will be included in the category of medical devices and made subject to marketing approval/certification requirements
4. Simplification of regulatory system of medical device manufacturing business from licensing to registration
5. Streamlining of QMS audit of medical devices

Risk-based Regulation (Modified)

GHTF Classes	Risk-based Classification	Pre-market	
		Class	Approval /Certification
Class A	Extremely Low Risk (X-Ray films, Surgical Instruments) 	"General" **(Class I)**	**Self-declaration (notify to PMDA)**
Class B	Low Risk (MRI, digestive catheters Ultrasound Diagnostic Devices)  	"Controlled" **(class II)**	**Registered Certification Body Certification**
Class C	Medium Risk (artificial bones, dialyzer)  	"Specially Controlled" **(class III & IV)**	**MHLW's Approval**
Class D	High Risk (pacemaker, artificial heart valves)  		

Extended to Part of Class C

Stand-alone software in J-PAL by Nov.24 2014

Handling of the Standalone Software on existing Pharmaceutical Affairs Law (JPAL)

- Standalone software is NOT a “medical device”
- Embedded software which is intended to operate the medical device is regulated as unbroken part of the Hardware (MD).

	SW Embedded in hardware	Standalone SW as medical device	Standalone SW as non-medical device
Japan	○	×	×
EU	○	○	○
US	○	○	○
Canada	○	○	○

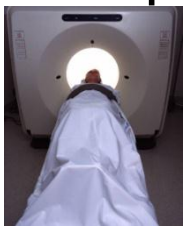
Revision for stand-alone software

Medical Device in Current J-PAL

Diagnostic Imaging Workstation

Processing, Archiving, and Display for Imaging Data of X-ray CT, MRI, PET, PET-CT

<example.>



Data of X-ray CT

Processing for 3D

3D imaging for Head Bone

Software

Hardware

Stand-alone Software is not MD.
Hardware with Embedded Software is MD

Revised

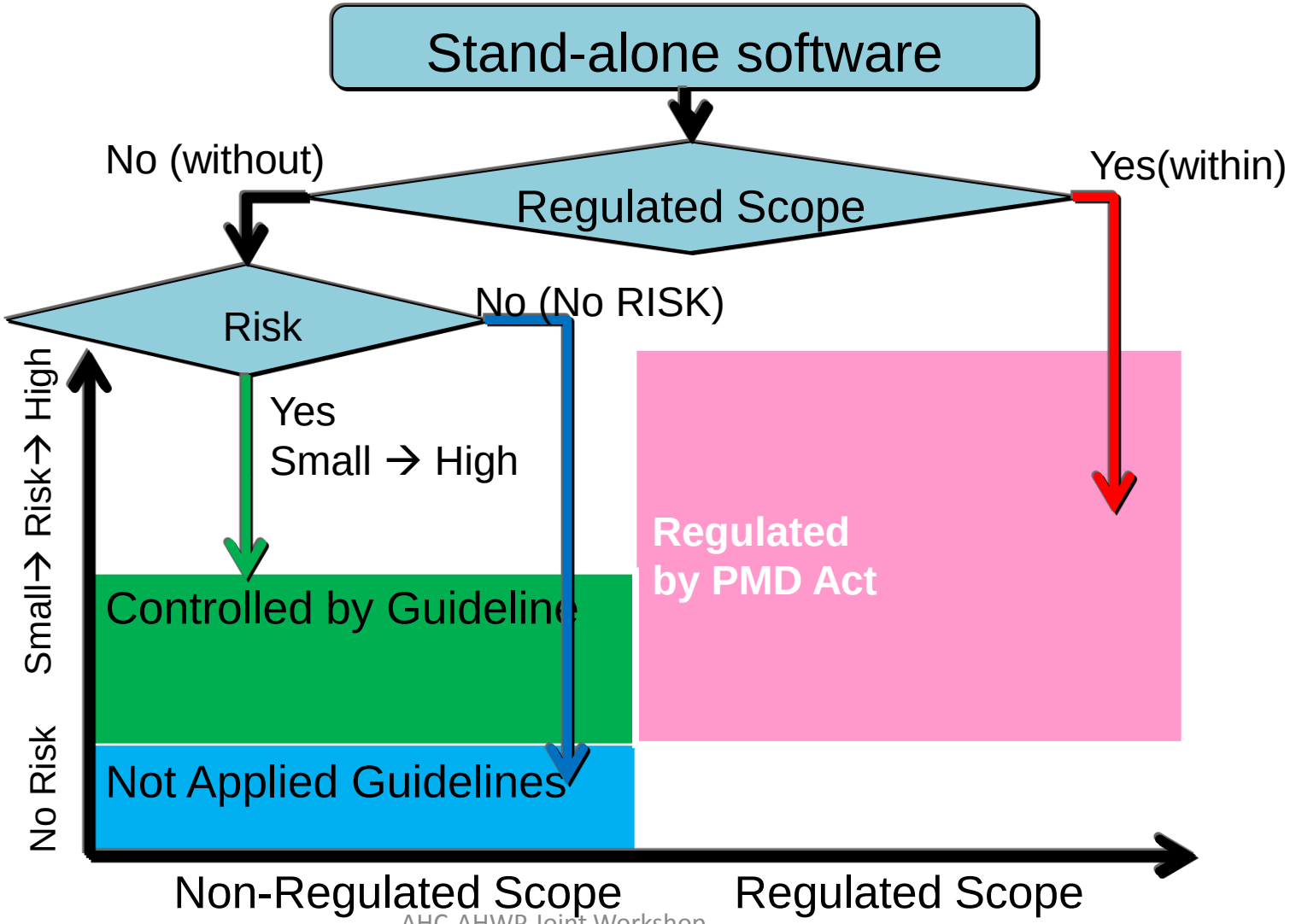
Stand-alone software

Software

Stand-alone software is regulated by PMD Act.

Scope of stand-alone software in JP

All Health Care software are medical Device?



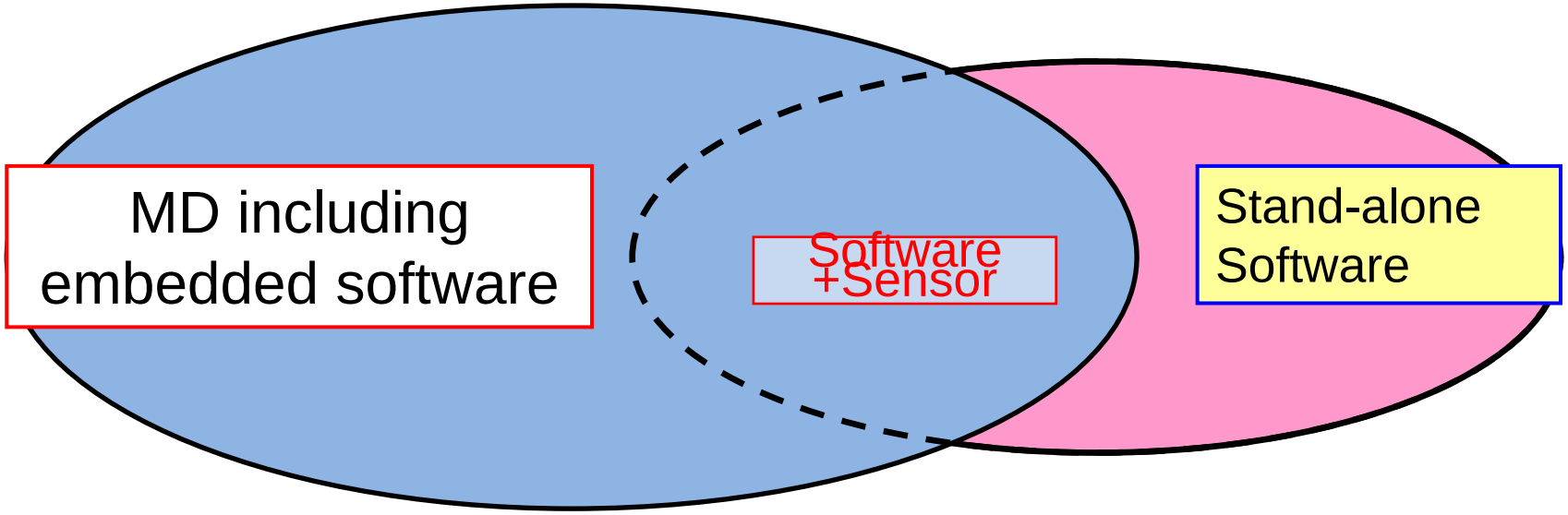
Scope of stand-alone software in JP

Annex List in PMD Act.
For Medical Devices Categoly

- Medical Instruments
- Medical Goods
- Medical Dental Material
- Sanitary Materials
- Programs
  - Program for Diagnostics
  - Program for Treatments
  - Program for Preventives

Scope of stand-alone software in JP

Software in PMD Act,

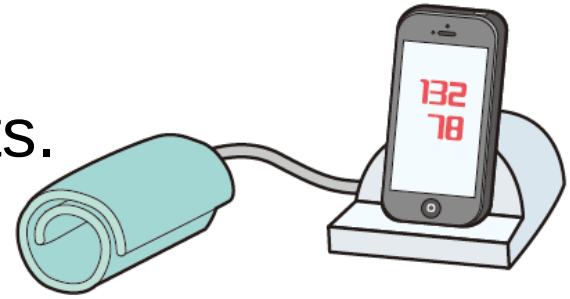


Same Controlled Level of current J-PAL

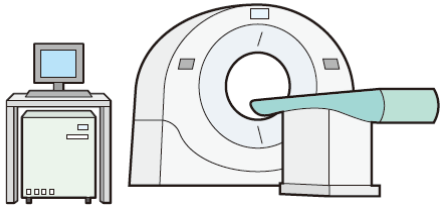
Scope of stand-alone software in JP

- How to apply PC and Mobile Goods with Sensor and Software

It is equivalent with Medical Instruments.
Sensor and Software is MD.



- Embedded Software in Medical Instruments
  - a part of Medical Instruments



- Control software for Medical Instruments to connected directly and via Internet to Medical Instruments
  - a part of Medical Instruments (software is part of MD)

Stand-alone software as MD

1. Stand-alone Software for processing the data provided by MD intended to Diagnostic or Treatment

i. **Diagnostic Imaging Software （not including displaying as reference or archiving intended to Medical Records)**

ii. **CADe（Computer-Aided Detection））**

iii. **CADx（Computer-Aided Diagnosis））**

iv. **Diagnostic Software to perform a statistical comparison with the normal condition group by the data of New Clear Medical Instruments.**

v. **Indication software of the severity of diabetes to processing the data by blood glucose meter.**

vi. **Diagnostic Data Processing software to processing the data by single or multi modality as Medical Diagnostic Devices.**

Stand-alone software as MD

2. Stand-alone Software of Planning and Supporting for Treatment

i. **Software of Planning and Supporting for Treatment by Imaging of X-ray CT or the other imaging instruments**

ii. **Radiation treatment planning system software**

iii. **Navigation software to neurosurgery using image**

iv. **Program for creating a preoperative planning of orthopedic surgery**

v. **Refractive surgery laser irradiation data creation program**

vi. **Programmed Automatically management system for a medication**

Stand-alone software as non-MD

1) **For medical record,**
   Data archiving and displaying software.
2) **Data processing software**
   (not including Imaging)
3) **Educational program**
4) **Supporting tools for informed consent to Patient**
5) **Maintenance program**
6) **Hospital Business Support program**
7) **Health Management program**
   and
8) **General Medical devices (Class I devices)**
   not regulated in revised regulation.

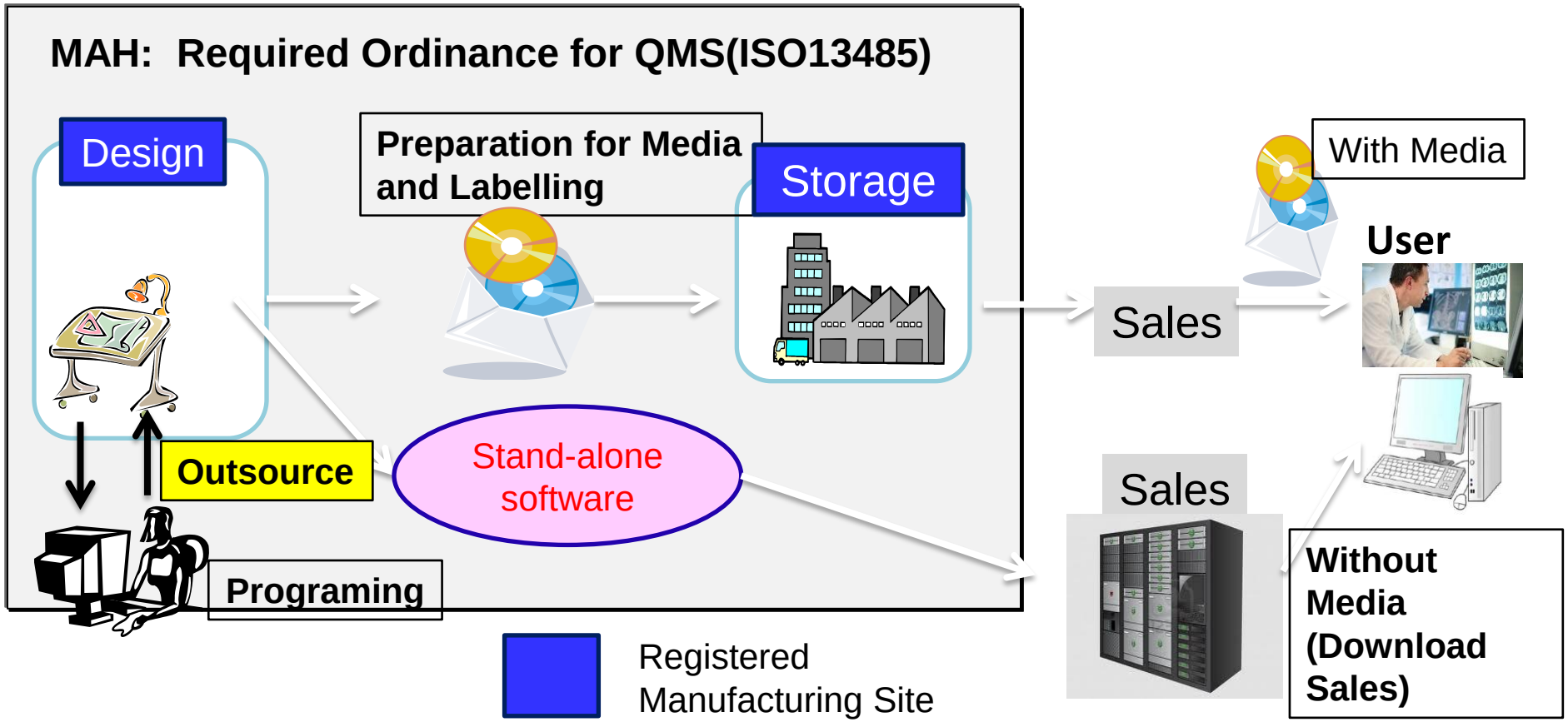
Definition and Classification

- Definition
  - Japanese Medical Device Nomenclature (JMDN) for Stand-alone software will be released by Nov. 25th.
  - 108 items are based on the current definition of Certification Products.
- Classification
  - Classification Rule is notified as No.0510-8 Dated 2013.5.10 (Original Notification No. 0720022).→ *Not Changed*.
  - For MD
    Rule 9. 10. 11. 12. equivalent with GHTF Rule
  - For IVD

CLASS	RISK LEVEL	EXAMPLES
III	High Individual Risk Moderate Public Health Risk	Cancer , HIV, HCV, Gene Diagnostics
II	Moderate Individual Risk Low Public Health Risk	Hb, Ht such as blood morphological examination, anti-Sm antibodies and the like autoimmune measurement
I	Low Individual Risk Low Public Health Risk	Clinical Chemistry Analyser(Depended on Conformity Assessment) , and the Others

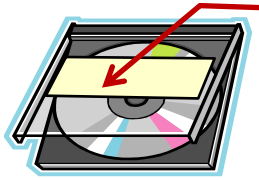
Business Requirements

- Business model with/without Media



Labelling Requirements for Label

- with Media



Labelling Required Contents of PMD Act

Displaying Required Contents of PMD Act

Sales Name
MAH Name
Certification number
Etc.

- without Media (Download Sales)

Download

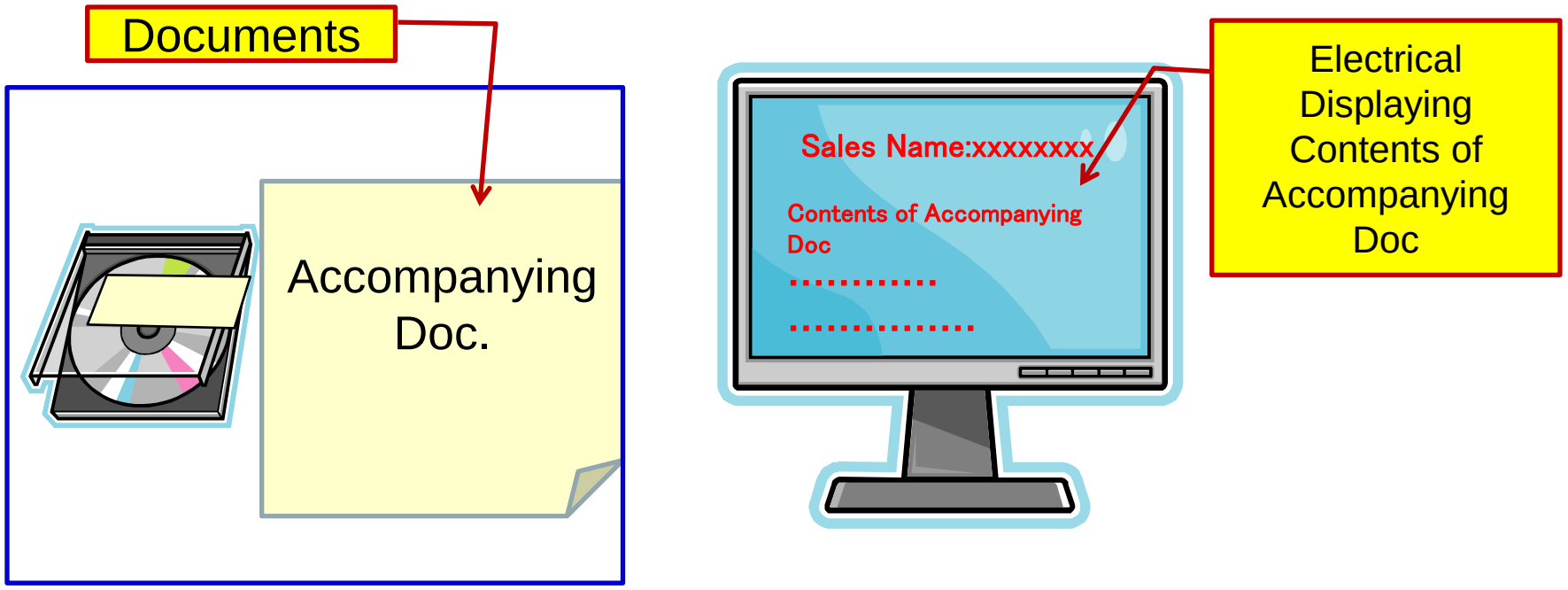
Displaying Required Contents of PMD Act

On demoand

Displaying Required Contents of PMD Act

Labelling Requirements for Accompanying Doc

- In the case of Japan,
  Specific Accompanying Documents are required by PMD Act..
  In the case of stand-alone software, Accompanying Documents are distributed as the following;



Advertisement for Stand-alone software

Without Media (Download Sales)

Licensed Sales Company shall inform the following items for the advertisement. (e.g. on Web site)

1) Licensed Sales Company Name and Address

2) Telephone number and the other contact

3) The others

XXX software
Advertisement

Sales: aaaa company co.
yyyyyy, Tokyo, Japan･
TEL 03-1234-5678
E-mail ･････@･･･.co.jp
The others:

Summary

Stand-alone software will be specified as MD after Nov. 25th 2014 in Japan.

So may many items are to be determined by Nov. 25

We need to follow these additional issues.

However,

we expect to modify the regulation for software step by step,

because it is new feature.

Thank you

Thank you very much
for your kind attention.

IMDRF Open stakeholder Meeting and Related Event

Tokyo: 2015.3.23-26

IMDRF Open stakeholder Meeting and Related Event

Kyoto: 2015.9.14-18 (TBD)