

# Software Regulation and Validation

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# Agenda

- 0. Introduction**
- 1. Qualification and Classification**
- 2. Low Risk Software**
- 3. Creating Certification Standards**
- 4. Pre-market Application and Validation**
- 5. Cybersecurity**

# Introduction of Keiichiro Ozawa

**Name:** *Keiichiro Ozawa*  
**Company Name:** *FUJIFILM Corporation*  
**Business Title:** *Regulatory Specialist*



## **Biography:**

- *Member of JFMDA Medical Device Software Working Group (The Japan Federation of Medical Devices Associations)*
- *Member of IMDRF SaMD Working Group (International Medical Device Regulators Forum)*
- *Chair of DITTA Medical Software WG (Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association)*
- *IEC Expert of TC62/SC62A/JWG7*

## 1-1. Qualification of Medical Device Software

### Revision of Pharmaceutical Affairs Law

- Japanese Pharmaceutical Affairs Law has been revised as “PMD Act” and it has been in effect since Nov. 25, 2014.
- One of the significant points of the revision was the implementation of revised GHTF Essential Principles (2012) which led to the *introduction of standalone medical device software* into the Japanese regulatory system.

# 1-1. Qualification of Medical Device Software

Software qualified as a medical device

Notification on the basic concept of the qualification of medical device software, MHLW, Nov. 14, 2014

● The intended use of the medical device software is based on the definition of the medical device, ... installed in general-purpose PC or handheld terminals".

1) Software which **creates indices, images, charts for diagnosis or treatment** by means of processing data from medical devices

2) Software which supports the decision of **treatment plan or treatment method** (including simulation software)

# 1-1. Qualification of Medical Device Software

Software qualified as a non-medical device

- 1) Software which transfers, stores and displays data from medical devices used as medical records
- 2) Software which processes or computerizes data except image data for the purpose other than diagnosis
- 3) Software for education
- 4) Software for patient explanation
- 5) Software for maintenance
- 6) Software for hospital business support
- 7) Software for health management
- 8) Software equivalent to General Medical Device (Class I equivalent)

## 1-2. Classification of Medical Device Software

PMD Act employs basic concept of GHTF rule for medical device classification.

→ Principles of Medical Devices Classification, GHTF, Nov. 2, 2012

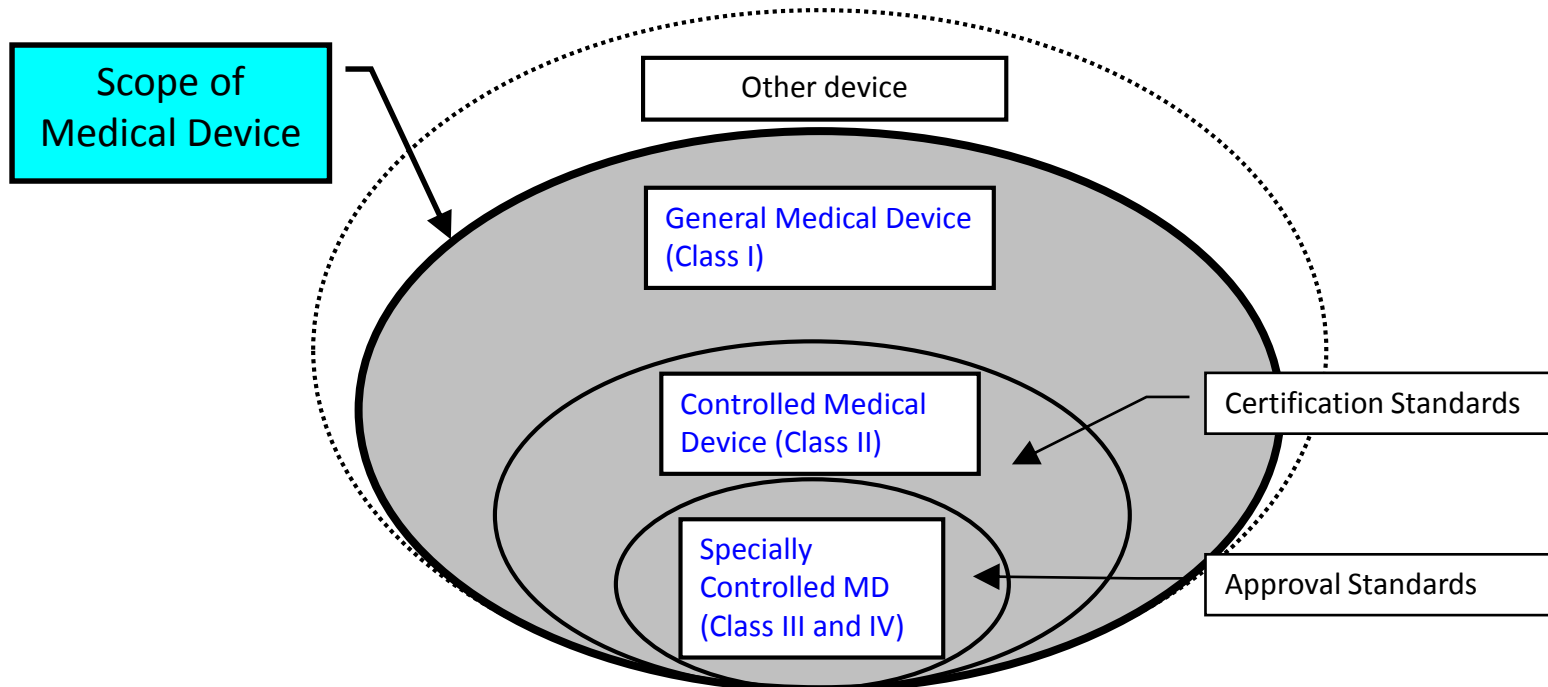
Notification on the amendment of the classification rule of medical devices, MHLW, May 10, 2013

It says on the top page, “The classification rule of medical devices has been stipulated based on the rule discussed in GHTF...”

And any other special rules has not been issued on the classification of medical device software. Therefore this rule should be applied for the medical device software.

## 1-2. Classification of Medical Device Software

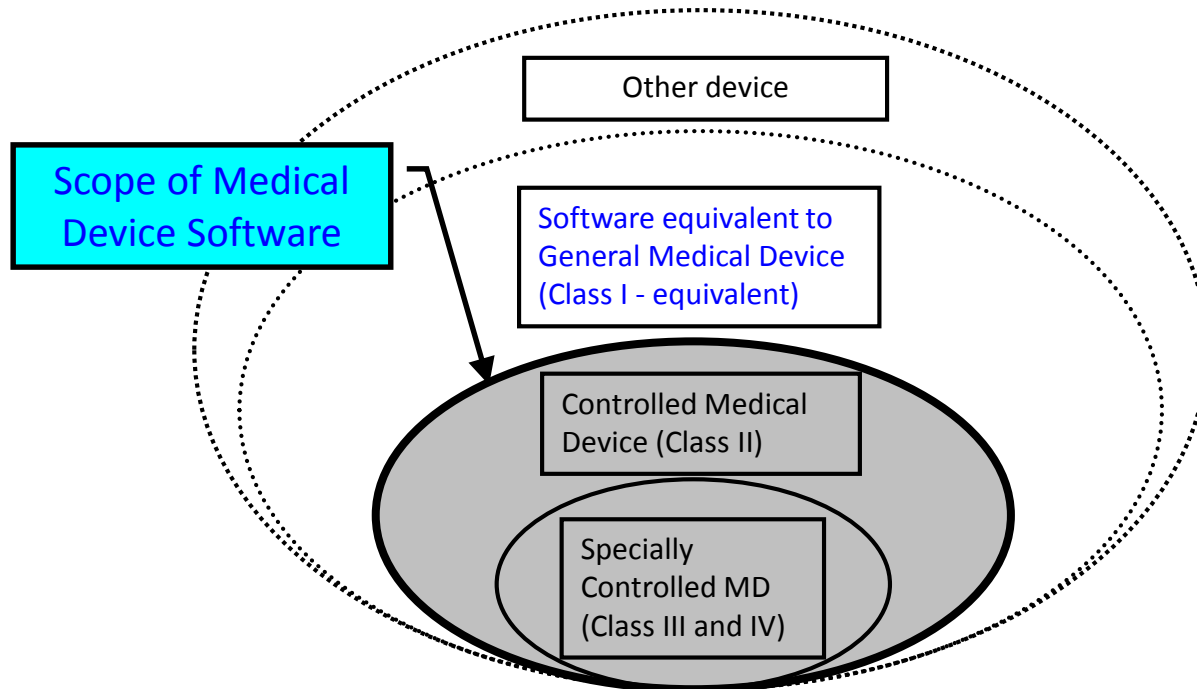
### General classification of *Medical Device*





## 1-2. Classification of Medical Device Software

### Scope of *Medical Device Software*



## 2-1. Low Risk Software

Software equivalent to Class I medical device

General Medical Device, Class I, has been **eliminated** from the medical device classification **for software**. It has little risk of affecting human life and health in case of the functional failure. This is the special classification rule only for the medical device software.

### Example

1. Software which performs eyesight test or color perception test by general-purpose PC or handheld terminals
2. Software which detects body motion by means of sensors of handheld terminals

...

## 2-1. Low Risk Software

The approach of USA for low risk software  
→ FDASIA Health IT Report, FDA, Apr., 2014

FIGURE 3: Overview of Proposed Health IT Priority Areas



## 2-2. Voluntary Standards by Private Sectors

What about Japan?

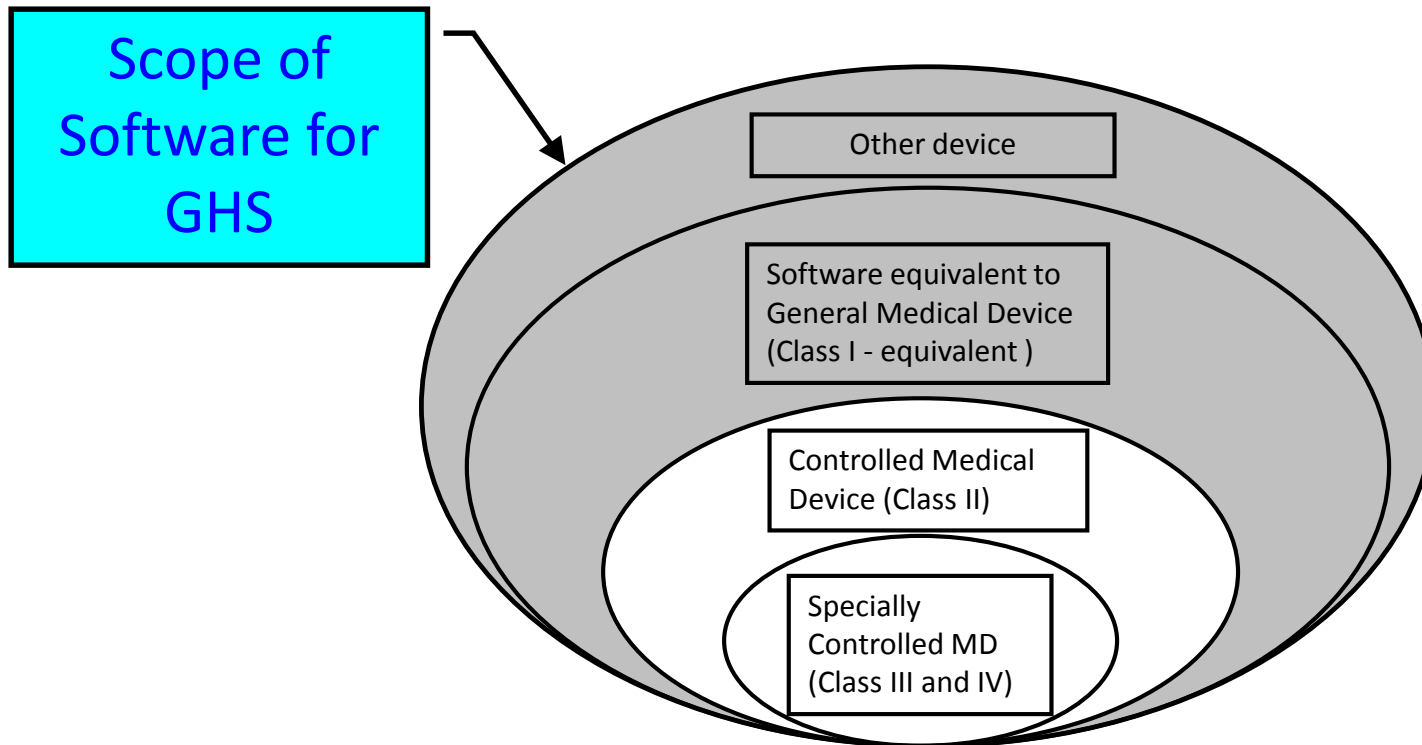
## 2-2. Voluntary Standards by Private Sectors

Good Health Software Promotion Council  
for **GHS (Good Health Software)**

1. Purpose is to **develop guidelines for the non-medical device software** so that software developers can provide good software to users.
2. The guidelines are applied to **quality management, risk management, software product safety and software lifecycle process**. (GHS Development Guidelines)

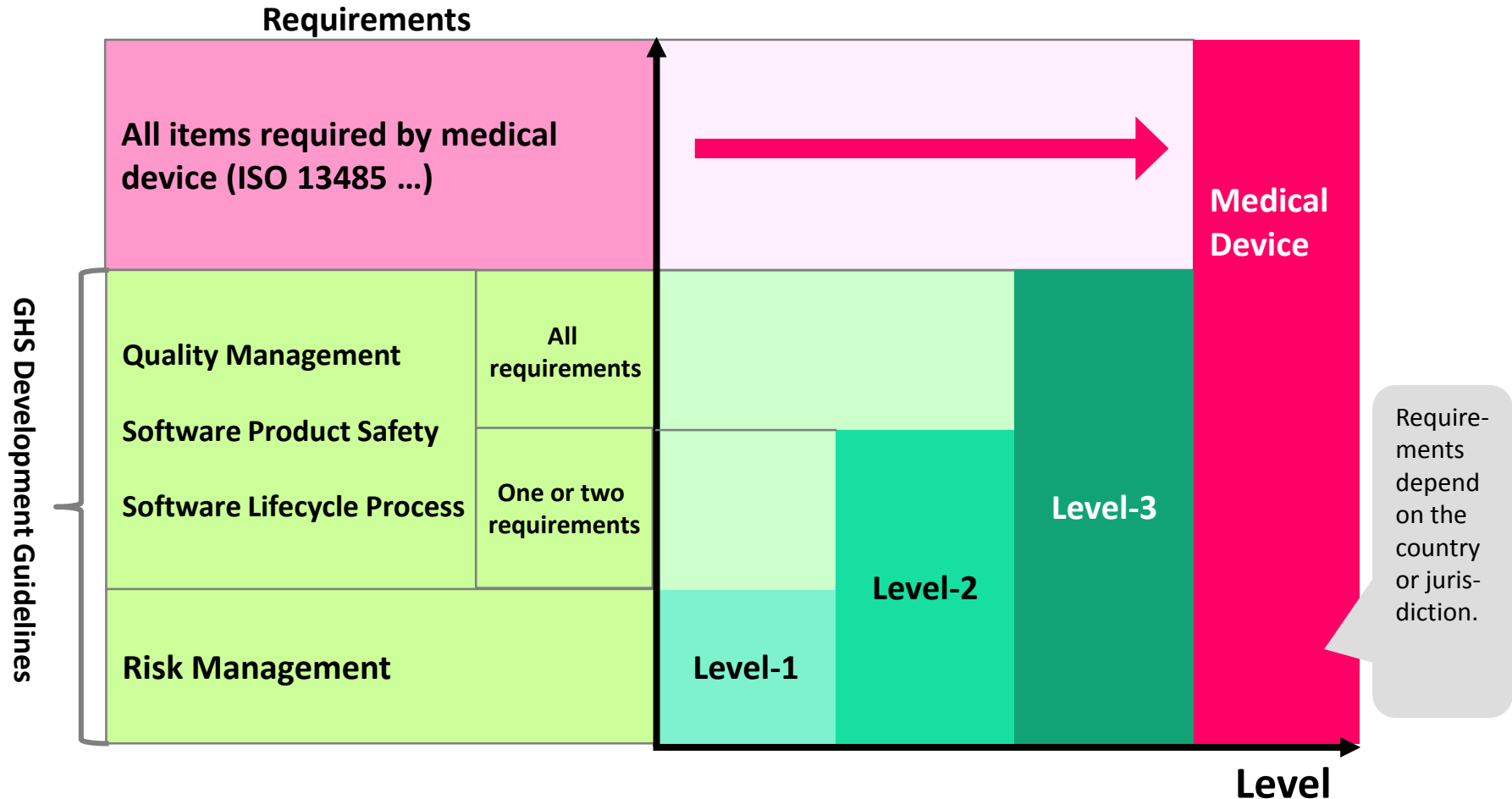
## 2-2. Voluntary Standards by Private Sectors

### Scope of *Software for GHS*



## 2-2. Voluntary Standards by Private Sectors

GHS Development Guidelines - Three conformance levels



## 2-2. Voluntary Standards by Private Sectors

### The list of conforming software on the website

The items of the list are

- Level (Level-1, 2 or 3)
- Registration number
- Product name
- Software version
- Company name
- URL of company website

■ ■ ■

GHSマークの表示例		GHSマークの商標権について
		GHSマークの商標権は一般社団法人ヘルスソフトウェア推進協議会が保有しています。GHSマークが不正に使用された場合には、当協議会はGHSマーク使用契約の解除その他必要な法的措置をとることができます。 また、GHSマーク適合の認定後、認定要件に対し適合が維持されていない場合には、当協議会は適切な是正措置を求めるとともに場合によっては認定の一時停止または取消を行うことがあります。

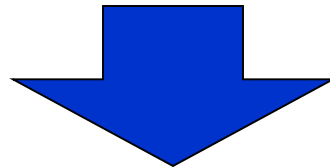
The list of conforming software

Level	登録番号	登録日	製品名	会社名	詳細
1	G1500011	2015-02-19	Product name	Company name	▶
1	G1500021	2015-02-19	Product name	Company name	▶
1	G1500031	2015-02-19	Product name	Company name	▶
1	G1500041	2015-02-19	Product name	Company name	▶
1	G1500061	2015-04-14	Product name	Company name 株式会社	▶
2	G1500072	2015-04-14	Product name	Company name	▶
2	G1500142	2015-04-14	Product name	Company name	▶
2	G1500082	2015-04-14	Product name	Company name	▶
2	G1500092	2015-04-14	Product name	Company name	▶



### 3. Creating Certification Standards

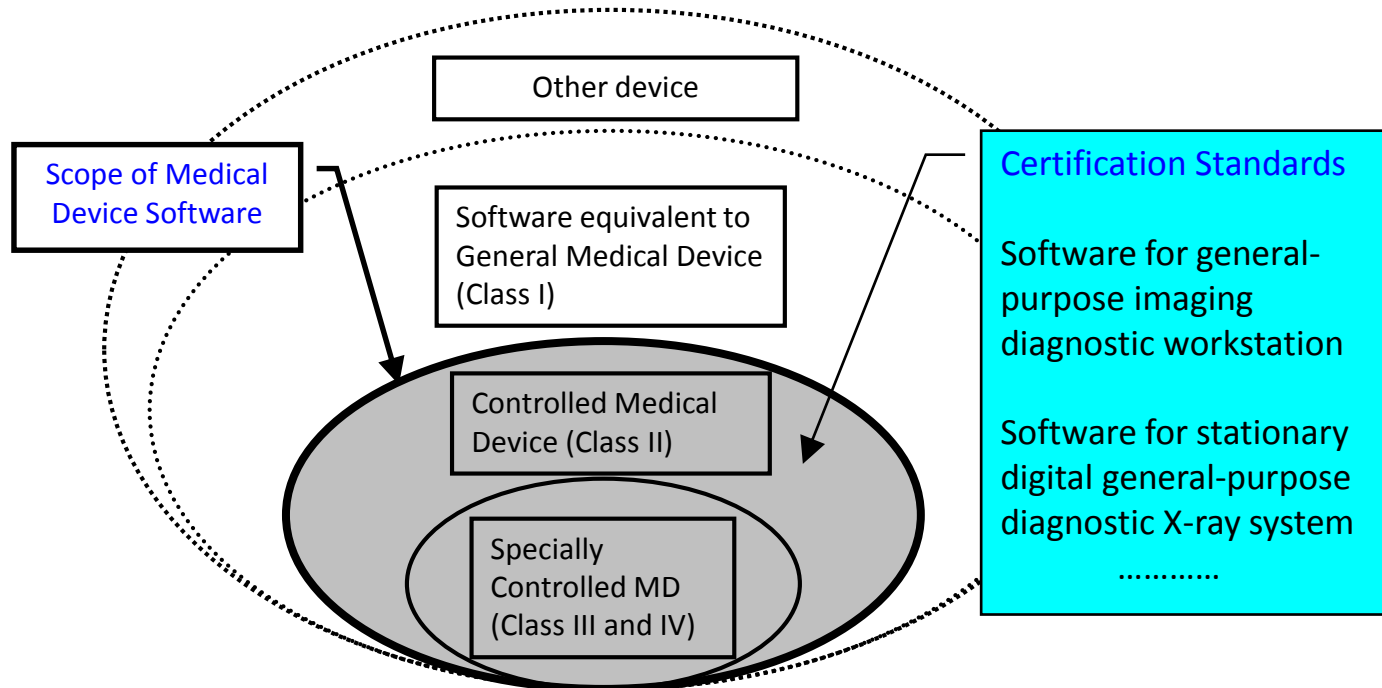
Qualification and classification rules have been stipulated. But it may take several years to have the devices reviewed by certification standards which require relatively short review term.



Expediting the premarket review process by creating the certification standards.

## 3. Creating Certification Standards

### Scope of Medical Device Software



### 3. Creating Certification Standards

- Current innovative progress of medical device software is so drastic.
- Creating every possible certification standard from hardware medical devices even though some standards may not be used.

- Certification Standards, 108 (total ~1370):

Name, applied standards, intended use and etc. All medical device software are Class II.

- JMDN (Japanese Medical Device Nomenclature), 150 (total ~4258):

Generic name, definition and etc. All medical device software with the certification standards are Class II.

\* The numbers are as of 2014.

### 3. Creating Certification Standards

[Example]

The corresponding hardware medical device

JMDN Code: 70030000

Name: General-purpose imaging diagnostic workstation

Applied standard: JIS C 6950-1 (IEC 60950-1)

Intended use: It computerizes human image information from image diagnosis medical devices and provides processed image information for medical care (excluding those with automatic diagnostic functions)

Medical device software

JMDN Code: 70030012

Name: Software for general-purpose imaging diagnostic workstation

Applied standard: JIS C 6950-1 (IEC 60950-1)

Intended use: It computerizes human image information from image diagnosis medical devices and provides processed image information for medical care (excluding those with automatic diagnostic functions)

## 4. Pre-market Application and Validation

PMD Act employs basic concept of GHTF for essential principles of safety and performance of medical device.

→ **Essential Principles of Safety and Performance of Medical Devices, GHTF, Nov. 2, 2012**

Notification on the essential principles of safety and performance of medical device, MHLW, Nov. 5, 2014

One of the new requirements of the amendment is **the introduction of medical device software** and it requires to ensure the repeatability, reliability and performance according to the intended use. And the requirement in the event of a single fault condition is described. These requirements are also described in B8 of GHTF document.

## 4. Pre-market Application and Validation

**Essential Principles Conformity Checklist is required for any medical devices.**

Essential Principles Conformity Checklist is in tabular format of Essential Principles dedicated for the medical device with its related information such as applicability, applied standards, documentation information, etc. And **it is required to be included in the pre-market application document.**

## 4. Pre-market Application and Validation

### Requirement for performance

#### **Essential Principles**

(Benefits of the medical devices)

#### **Article 6**

All known or foreseeable risks and undesirable effects shall be minimized as far as reasonably practicable and be acceptable when weighed against the intended benefits of medical devices under normal conditions of use.

→ Each application is required to describe the performance specification, standard, etc. related to this article in the checklist.

## 4. Pre-market Application and Validation

### V&V in pre-market application document

(Software for general-purpose imaging diagnostic workstation, Class II)

#### Performance evaluation

- Processing of images and information  
*image flip (vertical, horizontal), image rotation, image enlargement, gradation processing*
- Displaying images
- I/O with external devices

**→ Evaluation report accompanied with the application document**



## 4. Pre-market Application and Validation

### V&V in pre-market application document

(Software for radiation treatment planning system, Class III)

#### Performance evaluation

- Outlining
- Displaying geometric parameter
- Dose distribution calculation

.....

#### Safety evaluation

- Distance and length (JIS Z 4715: 2011, Sec. 7.1)
- Radiation dose (JIS Z 4715: 2011, Sec. 7.2)
- Format of date and time (JIS Z 4715: 2011, Sec. 7.3)

.....

**Evaluation report in  
the application document**



## 4. Pre-market Application and Validation

### Requirement for development lifecycle of software

#### Essential Principles

(Consideration of medical devices using programs)

#### Article 12

2 For devices which incorporate software the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, verification and validation to operate properly.

→ It will be mandatory that each application describes the conformity to the article in the application **from Nov. 25, 2017.**

## 4. Pre-market Application and Validation

### Requirement for development lifecycle of software

#### *How to describe the conformity to Article 12.2 in the application document*

*(Now **in progress** of discussion within JFMDA to suggest MHLW)*

Report as the implementation status of development lifecycle

1. Summarizing the conformity to **JIS T 2304** with its implementation status.
2. Picking up some significant requirements of **JIS T 2304** with its conformity.
3. Listing up all the requirements of **JIS T 2304** in a tabular form.

## 5. Cybersecurity

### Notification on cybersecurity, MHLW, April 28, 2015

#### 1. Fundamental policy

MAHs should ensure cybersecurity by ... **necessary risk control measures** ...

#### 2. Specific measures

(i) ... perform **protective risk management** to evaluate and reduce the risks ... **limiting the scope of connection** ... and **limiting the software, system or services to those that are confirmed** ...

(ii) ... which necessary cybersecurity is not ensured, **the users should be clearly informed of this issue** ...

(iii) In accordance with “Guidelines for the Security Management of Health Information Systems”, **provide HDOs with necessary information** ...

\* Translated from Japanese to English by JIRA (Japan Medical Imaging and Radiological Systems Industries Association) and all rights reserved.

## 5. Cybersecurity

### ***Guidance on how to implement the cybersecurity notification***

*(Now **in progress** of discussion within JFMDA to suggest MHLW)*

- Scope

Necessary consideration of cyber risk including network environment, intended use, operational environment, etc.

- Cybersecurity measurement

Manufactures shall conduct risk management and demonstrate it is acceptable.

- Post-market safety assurance

Manufactures are responsible for the cybersecurity of pre-owned devices.

- Providing information to users

Manufactures shall provide necessary information to users to assure the safety of the device.

**THANK YOU!**