Software Regulation and Validation

Keiichiro Ozawa

FUJIFILM Corporation
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

12/07/2016
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

- General Medical Device (Class I)
- Controlled Medical Device (Class II)
- Specially Controlled MD (Class III and IV)
- Other device

Scope of Medical Device

Certification Standards

Approval Standards
1-2. Classification of Medical Device Software

Scope of Medical Device Software

- Software equivalent to General Medical Device (Class I - equivalent)
- Controlled Medical Device (Class II)
- Specially Controlled MD (Class III and IV)
- Other device
2-1. Low Risk Software

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

- Promote the Use of Quality Management Principles
- Identify, Develop, and Adopt Standards and Best Practices
- Leverage Conformity Assessment Tools
- Create an Environment of Learning and Continual Improvement

Health IT Safety Center
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

- Other device
- Software equivalent to General Medical Device (Class I - equivalent)
- Controlled Medical Device (Class II)
- Specially Controlled MD (Class III and IV)
2-2. Voluntary Standards by Private Sectors

GHS Development Guidelines - Three conformance levels

<table>
<thead>
<tr>
<th>Requirements</th>
<th>Level-1</th>
<th>Level-2</th>
<th>Level-3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality Management</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Software Product Safety</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Software Lifecycle Process</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risk Management</td>
<td>One or two requirements</td>
<td></td>
<td></td>
</tr>
<tr>
<td>All requirements</td>
<td></td>
<td>All requirements</td>
<td></td>
</tr>
<tr>
<td>All items required by medical device (ISO 13485 ... )</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Requirements depend on the country or jurisdiction.
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

<table>
<thead>
<tr>
<th>Level</th>
<th>Registration number</th>
<th>Product name</th>
<th>Company name</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>G15000011</td>
<td>Product name</td>
<td>Company name</td>
</tr>
<tr>
<td>1</td>
<td>G15000021</td>
<td>Product name</td>
<td>Company name</td>
</tr>
<tr>
<td>1</td>
<td>G15000031</td>
<td>Product name</td>
<td>Company name</td>
</tr>
<tr>
<td>1</td>
<td>G15000041</td>
<td>Product name</td>
<td>Company name</td>
</tr>
<tr>
<td>1</td>
<td>G15000051</td>
<td>Product name</td>
<td>Company name</td>
</tr>
<tr>
<td>2</td>
<td>G15000072</td>
<td>Product name</td>
<td>Company name</td>
</tr>
<tr>
<td>2</td>
<td>G15000082</td>
<td>Product name</td>
<td>Company name</td>
</tr>
<tr>
<td>2</td>
<td>G15000092</td>
<td>Product name</td>
<td>Company name</td>
</tr>
</tbody>
</table>
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

- Other device
- Software equivalent to General Medical Device (Class I)
- Controlled Medical Device (Class II)
- Specially Controlled MD (Class III and IV)

Certification Standards
- Software for general-purpose imaging diagnostic workstation
- Software for stationary digital general-purpose diagnostic X-ray system
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)

.........
4. Pre-market Application and Validation

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**
  Manufatures 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!