Unique Device Identification (UDI): What is happening in Korea?

May 11, 2017

Young Kim
Synex Consulting Ltd.
Objectives

- The Ministry of Food & Drug Safety (MFDS) plans to introduce a UDI system to the Korean medical device regulation.

- This is to share information on the overall plan of MFDS and the current status of preparation.
Why is Korea interested in UDI?

• To improve patient safety
  – The UDI is a useful tool to improve patient safety by enabling more accurate identification of medical devices especially in circumstances where public safety management is needed, such as, adverse event reporting, recall and by disseminating information for safe use of devices.

• To level up international harmonization in medical device regulation
  – One of the most important policy directions for MFDS in medical device regulation.

• To improve accuracy in statistics on the medical device industry in Korea
  – The UDI can be instrumental in collecting more accurate information on the medical device industry efficiently.
  – The MFDS has imbedded the requirement for medical device companies reporting information on their distribution to MFDS.
UDI in Korea: Scope of Potential Utilizations

Korean UDI Database

- UDI Foundation: Labeling, Database Setup, Use in Adverse Event Reporting, Recall, Etc.
- Mapping with Reimbursement Codes
- Regular report to MFDS of medical devices distributed
- Use of UDI in logistics, electronic medical records, etc. (to be determined)

<table>
<thead>
<tr>
<th>Year</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
<th>2020</th>
<th>2021</th>
<th>2022</th>
</tr>
</thead>
</table>

May 11, 2017
The 2nd Korea-Japan Joint Symposium on Medical Products
The Lead Authority
Ministry of Food and Drug Safety (MFDS)

- MFDS has the exclusive authority for regulating medical devices.
- National Institute of Food & Drug Safety Evaluation (NIFDS) is the subordinate organization of MFDS to review Technical Documentation of medical devices.

- The offices of MFDS and NIFDS are located in the city of Osong, Chungbuk, 120km south of Korea.
The Co-Work Authorities

- Ministry of Food and Drug Safety
  Overall Regulations

- Ministry of Health and Welfare
  Overall Coordination in R&R

- HIRA
  Matching with Reimbursement Codes

May 11, 2017
The 2nd Korea-Japan Joint Symposium on Medical Products
MFDS is working on necessary regulations...

- **Medical Device Act**
  - Revised on December 2, 2016
to lay down the legal ground of UDI

- **Enforcement Decree**
  - A draft revision published on
February 7, 2017 to appoint a non-
government organization to support MFDS for
operation of the UDI database system

- **Enforcement Regulation**
  - MFDS is working on a revision to be
published for comments during Q2 2017

- **MFDS has yet to work on many more details...**
Terms Used in Korean Regulations

- UDI: Standard Code
- UDI Database: Medical Device Consolidated Information System (MDCIS)
  - For convenience of this presentation, this system will be referred to as MDCIS hereinafter
Major Changes in Medical Device Act
(Law No. 14330 revised on December 2, 2016)

<table>
<thead>
<tr>
<th>Article 20 Subparagraph 8</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Require UDI labeled on medical devices</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Article 31-2</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Require medical device manufacturers, importers, distributors and rental companies report to MFDS their sales records</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Article 31-3</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Medical Device Consolidated Information System (MDICS) to be established by this law</td>
</tr>
<tr>
<td>- Require manufacturers and importers register information on UDI and medical devices with the MDCIS</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Article 31-4</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Assign the task of operating the MDCIS to the MDCIS center to be newly established</td>
</tr>
</tbody>
</table>

**UDI Implementation Date:** The Prime Minister to determine an enforcement date within five years of the enforcement date of the revised Medical Device Act (Before December 2, 2021)
Proposed Changes in Enforcement Decree
(MFDS Public Notice No. 2017-57, February 7, 2017; to be finalized by June 2017)

Article 10-3

- Proposed to designate the Medical Device Information and Technical Assistance Center (MDITAC) to the organization for the Medical Device Information Consolidation System (MDICS)

- Proposed the work scope of the MDICS as follows:
  - Collect, process, use and release the information on approved medical devices and their distribution
  - Operate the Medical Device Information Consolidation System (MDICS)
  - Administer the standard codes of medical devices (UDI)
  - Develop software programs for submitting and registering information on UDI and
  - Develop plans for standardization of information on medical devices
  - Research, educate and publicity on UDI
  - Other activities determined as necessary by Minister of Food & Drug Safety
Medical Device Information and Technical Assistance Center (MDITAC)

• A non-profit organization established in 2012 under Medical Device Act

• MFDS supervises the responsibilities and performances of MDITAC

• MFDS has assigned MDITAC to the following tasks:
  – Technical review and certification of class 2 devices
  – Administration of Class 1 device reports
  – Analysis of adverse event reports
  – Training programs on medical device regulations, quality system, regulatory affairs professionals, etc.
  – Translation of international standards
  – Consultations for medical device R&D
Proposed Changes in Enforcement Regulation
(To be finalized by July 2017)

- To address the following scope of work and requirements:
  - Detailed regulations for operating the MDICS
  - Scope of information to be registered with MDICS
  - Submission of information on distribution of medical devices through the MDICS
More regulations coming up...

- MFDS is committed to harmonizing its UDI regulations internationally, e.g.,
  - IMDRF guidance
  - GS1 standards
**Phase-in Schedule 2019-2022 (draft)**

**UDI begins with high-risk devices**

<table>
<thead>
<tr>
<th>Descriptions</th>
<th>Class 4*</th>
<th>Class 3</th>
<th>Class 2</th>
<th>Class 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report to MFDS information on medical device sales</td>
<td>Manufacturer/Importer</td>
<td>2018</td>
<td>2019</td>
<td>2020</td>
</tr>
<tr>
<td>Distributor/Rental Company</td>
<td>2019</td>
<td>2020</td>
<td>2021</td>
<td>2022</td>
</tr>
<tr>
<td>Labeling UDI and Information Submission to the Korean UDI Database</td>
<td>2019</td>
<td>2020</td>
<td>2021</td>
<td>2022</td>
</tr>
</tbody>
</table>

*MFDS may designate at its discretion lower-class devices for earlier adoption of UDI.*
UDI requires big changes for companies in Korea....
Thank you!

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www.synex.co.kr
UDI and Traceability
From view of Medical Device Industries

The Japan Federation of Medical Devices Associations
Executive Director
EISHI HARASAWA (Mr.)
A globally harmonized and consistent approach to UDI is Expected to increase patient safety and help optimize patient care by facilitating the;

a, traceability of medical devices, especially for field safety corrective actions,

b, adequate identification of medical devices through distribution and use,

c, identification of medical devices in adverse events,

d, reduction of medical errors,

e, documenting and longitudinal capture of data on medical devices,
Summary of UDI Implementation in Medical Devices Industry in Japan

1980s

| 1999 |
Guideline; Medical Device standardized code

2000

Database for All Healthcare Products started by MEDIS-DC
MEDIS-DC; Medical Information System Development Center

2001

Revised Guideline (JFMDA) in 2006

2006

MHLW issued “Guideline for Barcode Labeling of Medical Devices” in March 2008

2007

Published Practical Use Manual (JFMDA) in 2009

2008

2009

2010

| 2016 |
Revised Manual (JFMDA) in 2016

Started “UDI and Traceability Promotion Conference” (JFMDA)
Barcode Labeling and Register in the Database of Medical Devices in 2016

◆ **Barcode Labeling**

<table>
<thead>
<tr>
<th>Package</th>
<th>%</th>
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<tbody>
<tr>
<td>Primary Package</td>
<td>86.4%</td>
</tr>
<tr>
<td>Sales Package (Inner and outer)</td>
<td>94.5%</td>
</tr>
</tbody>
</table>

◆ **Register in MEDIS database**

<table>
<thead>
<tr>
<th>Devices</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Devices</td>
<td>77.2%</td>
</tr>
</tbody>
</table>

MEDIS-DC; Medical Information System Development Center
Current Situation in Japan
( hospitals, wholesale merchants, makers )

MEDIS-DC Database

Internet

MEDIS-DC ; Medical Information System Development Center
Current Situation in Japan
(Amount Ratio of Medical Materials in a Hospital)

Amount Ratio of Medical Materials in a Hospital (over 500 bets)

- Surgery Department: 47%
- Radiology Department: 16%
- Ward: 15%
- Endoscopy related: 8%
- Others: 16%

Materials Department
Pharmaceuticals Department
Ward
Surgery Department
Radiology Department
Center Materials Department

Medical Devices
Pharmaceuticals
Medical Device Logistics Service

JFMDA
The Japan Federation of Medical Devices Associations
Current Situation in Japan
( Outsourcing of Medical Logistics Service in Hospital )

Growth Rate

Penetration Rate

Source; Medical related service actual condition survey report 2015 by Japan Health Enterprise Foundation
Current Situation in Japan
( Intended Use of UDI )

JAHID conducted a questionnaire survey for 270 general hospitals (over 300 bets) in 2012

- Prevent medical accidents
- Application for reimbursement fee
- Consumption management of medical materials
- Secure traceability
- Management of expiration date of inventory
- Stock processing · purchase processing
- Order document verification at the time of arrival
- Others

JFMDA
The Japan Federation of Medical Devices Associations
Current Situation in Japan

The UDI have been widely used in large hospitals, not in the small and medium-sized hospitals in Japan.

In Japan, many local codes including codes used in hospitals are used, and many hospitals outsource their medical material management. Although DI of the standard code (GS1) linked with the local code is used, PI (lot number or serial number) is still not used much.

Now, the Key is to promote the benefit of GS1 product identification & barcodes and encourage healthcare providers and hospitals to use them.
Next Step; As “Team Japan”

In December 2016, the Medical Product Identification and Traceability Promotion Conference consisting of all stakeholders of industry, academia, medical care and public administration started by the call of JFMDA.

We need to make efforts to improve medical quality, ensure patient safety, and improve medical efficiency.

It is our belief that now is the time for Japanese healthcare systems to take action as TEAM JAPAN.
Regulatory requirements for medical device software in Korea

11th May 2017
Prepared by MinYong Choi
Head of Healthcare, BSI Group Korea
Agenda

- Regulatory Authority
- Definition of Medical Device
- Regulatory Scope for Medical Device Software
- Medical Device Regulations Framework
- MFDS Notifications for Medical Device Software
- MFDS Guidelines for Medical Device Software
Introduction of MinYong Choi

Head of Healthcare, BSI Group Korea

• T: +82 2 6271 4020, F: +82 2 777 4123
• E: minyong.choi@bsigroup.com

Background:

• 2016~Present  BSI Group Korea, Head of Healthcare
• 2016~Present  IEC TC 62 SCA Committee Member
• 2016~Present  IEC SyC AAL Committee Member
• 2012~2016  UL Korea, Medical Solutions, Business Development Manager
• 2005~2011  KFDA (MFDS), Medical Device Evaluation Department, Technical Reviewer
Regulatory Authority

Korea MFDS (Ministry of Food & Drug Safety), http://www.mfds.go.kr
Definition of Medical Device

Medical Device Act, Article 2 (Definition)

"의료기기"란 사람이나 동물에게 단독 또는 조합하여 사용되는 기구·기계·장치·재료 또는 이와 유사한 제품으로서 다음 각 호의 어느 하나에 해당하는 제품을 말한다.

The term "medical device" in this Act means an instrument, machine, apparatus, material, or any other similar product specified in the following subparagraphs as one used, alone or in combination, for human beings or animals:

Regulatory Scope for Medical Device Software

Medical Device Scope
- Hardware
- Software
- SaMD
- Mobile App

Wellness Device Scope
- HW
- SW
- Health SW
- Mobile App
Medical Device Regulations Framework

1. National Assembly
   - Medical Device Act
     - Act # 13698
     - RD 2015-12-29, AD 2016-12-30

2. President
   - Enforcement Ordinance
     - Presidential decree # 27209
     - RD 2016-05-31, AD 2016-05-31

3. Prime Minister
   - Enforcement Regulation
     - Prime minister decree # 1354
     - RD 2017-01-04, AD 2017-01-04

4. Minister
   - MFDS Regulations (Notifications)
     - Published 23 Notifications

5. Director
   - MFDS Guideline Documents
     - Published 469 Documents
## MFDS Notifications for Medical Device Software

<table>
<thead>
<tr>
<th>Notification ID</th>
<th>Title of Notification</th>
<th>Published/Revised Date</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>2016-132</td>
<td>의료기기 허가 신고 심사 등에 관한 규정</td>
<td>2016-12-07</td>
<td>Medical Device Registrations, Technical Documentations</td>
</tr>
<tr>
<td>2016-156</td>
<td>의료기기 제조 및 품질관리 기준</td>
<td>2016-12-30</td>
<td>GMP, Quality Management System</td>
</tr>
<tr>
<td>2017-6</td>
<td>의료기기 품목 및 품목별 등급에 관한 규정</td>
<td>2017-01-24</td>
<td>Medical Device Classification</td>
</tr>
<tr>
<td>2016-2</td>
<td>의료기기 부작용 등 안전성 정보 관리에 관한 규정</td>
<td>2016-01-14</td>
<td>Reporting for Adverse Event or Safety Information</td>
</tr>
<tr>
<td>2015-115</td>
<td>의료기기의 전기 기계적 안전에 관한 공통기준규격 [별표 1]</td>
<td>2015-12-31</td>
<td>IEC 60601-1:2012, ED 3.1</td>
</tr>
</tbody>
</table>
MFDS Notification #2016-132

- Clause 9 (Shape & Structure) 모양 및 구조
  - Software Structure (Architecture) and Functions

- Clause 10 (Raw Materials) 원재료
  - Software Name, Version and Operating Environment

- Clause 13 (Instructions for Use) 사용방법
  - Software UI Pictures, Description of Functions and Use Instructions

- Clause 29 (Attached Documents Requirements) 첨부자료의 요건
  - Software Validation Report using Report Form in Appendix 13
MFDS Notification #2016-132

• Clause 55 (Exemptions of Medical Device Selling Business License) 의료기기 판매업 신고가 면제되는 의료기기
  • Mobile Medical Apps using self-diagnostics
  • Devices (Mobile phone, Tablet PC, PC, …) including Mobile Medical Apps using self-diagnostics

• Clause 59 (Permission of Performance Upgrade/Improvement) 성능개선 허용 대상
  • Software changes or upgrades can be allowed.
  • The medical device related to the software have to be approved the changes or upgrades through the medical device change registration process before the software changes or upgrades.
• Appendix 3 Minor Changes for Software (Self Control Cases)
  • 36. Bug fix on mobile medical apps
  • 37. Version changes by bug fix on medical device software without any functions changes and safety/performance effects
  • 38. Version changes by modification of graphic user interfaces (color, menu position, ...) without any functions changes and safety/performance effects
  • 52. Modification of graphic user interfaces (color, menu position, ...) without any functions changes and safety/performance effects
  • 103. Version changes by additions of multi-language data without any functions changes and safety/performance effects
MFDS Notification #2016-132

- Appendix 10 STED: Summary Technical Documentation
- 2.7.7 Summary of Software Verification and Validation

<table>
<thead>
<tr>
<th>Process</th>
<th>Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Software Design &amp; Development</td>
<td>Software Planning</td>
</tr>
<tr>
<td></td>
<td>Software Requirement Specification</td>
</tr>
<tr>
<td></td>
<td>Software Architecture Design</td>
</tr>
<tr>
<td></td>
<td>Software Detail Design</td>
</tr>
<tr>
<td></td>
<td>Software Testing/Verification and Validation</td>
</tr>
<tr>
<td></td>
<td>Software Release</td>
</tr>
<tr>
<td>Software Maintenance</td>
<td>Change, Problem Resolution</td>
</tr>
<tr>
<td></td>
<td>Documentation</td>
</tr>
<tr>
<td></td>
<td>Configuration Management</td>
</tr>
</tbody>
</table>

ISO 13485

ISO 14971
## Medical Device Software Validation Report

<table>
<thead>
<tr>
<th>Device Classification</th>
<th>Software Name &amp; Version</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Deployed on Device</td>
<td>[ ] SaMD</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Software Type</th>
<th>[ ] Control</th>
<th>[ ] Measurement</th>
<th>[ ] Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Diagnose</td>
<td>[ ] Data Processing</td>
<td>[ ] Data Transmission</td>
<td></td>
</tr>
<tr>
<td>[ ] Data Reception</td>
<td>[ ] Display</td>
<td>[ ] Others</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Software Safety Classification</th>
<th>[ ] Class A</th>
<th>[ ] Class B</th>
<th>[ ] Class C</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Intended Purpose of Software</th>
<th>Software Operation Environment</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Software Design &amp; Development</th>
<th>Software Planning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Software Requirement Specification</td>
<td>Software Architecture Design</td>
</tr>
<tr>
<td>Software Detail Design</td>
<td>Software Testing/Verification and Validation</td>
</tr>
<tr>
<td>Software Release</td>
<td></td>
</tr>
</tbody>
</table>

## Software Risk Management

<table>
<thead>
<tr>
<th>Software Risk Management</th>
<th>Software Configuration Management</th>
</tr>
</thead>
</table>

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**Appendix 13 Software Validation Report**

**Report Form #13**

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MFDS Notification #2016-156

Criteria for Medical Device Manufacturing & Quality Management

• Based on ISO 13485:2003
  • 6.3 Infrastructure
  • 7.5.2 Validation of processes for production and service provision
  • 7.6 Control of monitoring and measuring device
Medical Device Classification

- This notification classify specific medical device softwares as medical devices

A26430.03 의료영상전송장치소프트웨어 [2]
Picture archiving and communication system, image processing, software

A software which is intended to save, expand, reduce, analyze, transmit and print medical images
**MFDS Notification #2016-2**

**Reporting for Adverse Event or Safety Information**

- **Medical Device Problem Codes**

<table>
<thead>
<tr>
<th>#</th>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
<th>Level 4</th>
<th>Level 5</th>
<th>Level 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2914 기기의 작동 문제(Device Operational Issue) 기기 작동과 관련된 기존에서의 편향과 관련된 문제 (예: 배치, 연결, 전기, 컴퓨터 소프트웨어, 주입/흐름, 출력, 보호장구, 부적합 문제); Issue associated with any deviations from specifications relating to device operations (e.g. deployment, connection, electrical, computer software, infusion/flow, output, protective measure, and incompatibility issues)</td>
<td>2814 기기의 작동 문제(Device Operational Issue) 기기 작동과 관련된 기존에서의 편향과 관련된 문제 (예: 배치, 연결, 전기, 컴퓨터 소프트웨어, 주입/흐름, 출력, 보호장구, 부적합 문제); Issue associated with any deviations from specifications relating to device operations (e.g. deployment, connection, electrical, computer software, infusion/flow, output, protective measure, and incompatibility issues)</td>
<td>1112 컴퓨터 소프트웨어 문제(Computer Software Issue) 기기 성능 또는 다른 기기와의 통신에 영향을 미치는 문서화된 프로그램, 코드 및/또는 소프트웨어 시스템과 관련된 문제; Issue associated with written programs, codes, and/or software system that affects device performance or communication with another device.</td>
<td>2880 응용프로그램 문제(Application Program Issue) 의도된 용도 내에서 기기의 성능을 충족시키기 위한 소프트웨어 또는 응용프로그램에 대한 요구사항과 관련된 문제; Issue associated with the requirement for software to fulfill its function within an intended use or application.</td>
<td>3013 소프트웨어 설치 문제(Problem with Software Installation) 기기의 원활한 기능수행을 가능하게 하는 방법으로 기기 소프트웨어를 설치하는 것과 관련된 문제; 설치 소스는 제조업체 또는 사용자가 될 수 있다; Issue associated with installing the device software in a manner that allows full functioning of the device. Source of installation could be manufacturer or user.</td>
<td></td>
</tr>
<tr>
<td>#</td>
<td>Level 1</td>
<td>Level 2</td>
<td>Level 3</td>
<td>Level 4</td>
<td>Level 5</td>
<td>Level 6</td>
</tr>
<tr>
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<td>---------</td>
<td>---------</td>
</tr>
<tr>
<td>26</td>
<td></td>
<td></td>
<td></td>
<td><strong>3014</strong> 프로그래밍 문제(Programming Issue) 기기의 기능 수행을 위한 기재된 요구 또는 목표를 충족시키기 위한 서면 프로그램 코드 또는 응용프로그램 소프트웨어와 관련된 문제. 여기에는 운영 체제와 관련된 문제는 포함되지 않는다; Issue associated with the written program code or application software used to satisfy a stated need or objective for functioning of the device. These do not include issues associated with the operating system.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>27</td>
<td></td>
<td></td>
<td></td>
<td><strong>1495</strong> 부정확한 소프트웨어 프로그래밍 계산(Incorrect Software Programming Calculations)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>28</td>
<td></td>
<td></td>
<td></td>
<td><strong>1189</strong> 소프트웨어 문제로 인한 용량 계산 오류(Dose Calculation Error due to Software Problem)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>...</td>
<td></td>
<td></td>
<td></td>
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MFDS Notification #2015-115

MFDS Standard for Electrical & Mechanical Safety

- Based on IEC 60601-1:2012, ED 3.1
  - Clause 14 PEMS (PROGRAMMABLE ELECTRICAL MEDICAL SYSTEM)

<table>
<thead>
<tr>
<th>Device Class</th>
<th>Day of Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class 4</td>
<td>2015-01-01</td>
</tr>
<tr>
<td>Class 3</td>
<td>2015-07-01</td>
</tr>
<tr>
<td>Class 2</td>
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MFDS Guidelines for Medical Device Software
### MFDS Guidelines for Medical Device Software

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<td>2017-07-31</td>
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MFDS Guideline B1-2015-5-229

Software Requirements for Medical Device Registration

- Scope of Application
- Terms & Definitions
- Software Safety Class
- Technical Documentation Guide
- Software V&V Report
- Technical Documentation Examples
MFDS Guideline B1-2015-5-229

Medical Device Software Characteristics

Installation Characteristics
- Deployed on Device
- SaMD

Functional Characteristics
- Control
- Measure, Analysis, Diagnosis
- Data Processing, Transmission, Reception
- Display

Safety Class
- Class A
- Class B
- Class C

Risk Management
Wellness Devices

• Criteria for determining Wellness Devices
• Criteria for Wellness Devices regulated as Medical Devices
  • Third level 14 black non bold, teal bullet
  • Scope of application
  • Definition of wellness device
  • Identification criteria for wellness device
  • Examples for wellness device
  • Process for official questioning to MFDS
  • Recommendations for safer use of wellness device
### Definitions

#### Medical Device

A device like any instrument, machine, contrivance, or material which is intended to be used for human beings or animals by itself or combination with others

- For the purpose of diagnosis, therapy, alleviation, treatment, or prevention of the illness
- For the purpose of diagnosis, therapy, alleviation, or compensation of the injury or disability
- For the purpose of test, replacement, or modification of the structure or functions of the body
- For the purpose of control of the conception

#### Wellness Device

A device like any instrument, machine, contrivance, material, software, or application which is intended to be used for human beings by itself or combination with others

- For the purpose of maintaining or improving of the general healthy condition or activity
- For the purpose of inducing of the healthy lifestyle or habit
- For the purpose of supporting self management for **chronic disease**

**Chronic disease:** Cardiac disorder, Hypertension, Hypotension, Diabetes, …
General principle for determination criteria

- The wellness device shall be identified by the intended use of the device and the potential hazards which are included in the device.
High level potential hazards

- Leading to the biocompatibility issue
- Being used invasively
- Leading to the injury or illness during the fault condition
- Monitoring the emergency situation
- Controlling or modifying the device characteristic or function
Wellness device segmentation

- General health management
  - Be used for Sports, Leisure purpose
  - Provide Medical information
  - Improve physical function
  - Measure or analyze biological information
- Self management for chronic disease
  - Support management for chronic disease
  - Provide information for chronic disease
MFDS Guideline A0-2015-5-006

MFDS Recommendations for Wellness Device Manufacturers

• MFDS recommends that the wellness device manufacturer should establish the quality management system for ensuring the device quality and safety.

• The quality management system should include the procedures related to the post-market surveillance and vigilance system.

• The below recommended caution sentence should be attached on the wellness device. (or should be displayed in the wellness device.)

This device is not a medical device.
This device can't be used for the diagnosis of illness.
You shall receive a medical treatment from the medical specialist to get the diagnosis of your illness correctly.
Mobile Medical Apps
• Criteria for determining Mobile Medical App

MFDS Guideline A0-2013-5-006

Yes

Mobile Medical App

Medical Device

No

Mobile App

Non-Medical Device
MFDS Guideline A0-2013-5-006

Smart Phone -> Control -> Medical Device
MFDS Guideline A0-2013-5-006

Display
Save
Analysis

Smart Phone

Data

App

Data Transmission

Medical Device
MFDS Guideline A0-2013-5-006

Smart Phone

Integrated Devices

App

Sensor
Cuff
Electrode
MFDS Guideline A0-2013-5-006

Smart Phone

Camera

SpO2 Sensor

Speaker

App
MFDS Guideline A0-2013-5-006

Medical Device → Data Input → App

Data

Smart Phone

Diagnosis
Determine Therapeutic Method
Requirements for Mobile PACS Registration

Requirements for PACS Registration

MFDS Guideline B1-2015-5-105

MFDS Guideline B1-2015-5-107

MFDS Guideline B2-2007-5-004
Thank you.

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Tel     +82 2 6271 4020
Medical Software Regulation in Japan

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
- Chair of DITTA Medical Software WG (Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association)
- IEC Expert of TC62/SC62A/JWG7
- Member of AHWP WG1
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*

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

Scope of Medical Device

Certification Standards

Approval Standards
1-2. Classification of Medical Device Software

Scope of Medical Device Software

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

- 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*

- **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

- **Level-1**: All items required by medical device (ISO 13485 ...)
- **Level-2**: Quality Management, All requirements
- **Level-3**: Software Product Safety, All requirements

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

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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

5/11/2017
2nd Korea-Japan Joint Symposium on Medical Products
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 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.
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!