What is reliance and why is it important? - The role of standards-

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Agenda

- Reliance and international standards
- IMDRF Activity - Especially for international standards
- International standards in Japanese regulation - Case study for third party certification
Reliance and international standards

- Harmonized Regulatory Framework
- Recognized International Standards
- Review/Audit/Post-market Activities
- Decision-Making
  - Possible Elements for Reliance
IMDRF Activity (international standards)

**IMDRF Strategic Plan 2021-2025** *(IMDRF/ MC/N39 FINAL:2020)*

◆ **Key Objectives**

1) Managing regulatory challenges for medical devices and innovative technologies by providing timely and appropriate guidance.
   ⇒ To work collaboratively with various external stakeholders.
   (e.g., standards development organizations)
   ⇒ International standards continue to be effective tools in conforming to essential principles for safety and performance for medical devices.
   ⇒ To promote further development of useful and relevant international standards for innovative technologies.

2) Strengthening post-market surveillance for medical devices and implement regulatory life cycle processes.
IMDRF Activity (international standards)

Outlining use of standards

- Statement regarding use of below international standards in IMDRF jurisdiction
  (IMDRF/MC/N25, N34~N38 FINAL: 2015)

  These standards are recognized by majority of IMDRF jurisdictions
  - Good clinical practice : ISO 14155:2011
  - Medical device software : IEC 62304:2006,
  - Medical electrical equipment : IEC 60601-1
  - Biological evaluation : ISO 10993
  - Sterilization of healthcare products_- Radiation : ISO11137-1: 2006

- Survey regarding the number of international standards such as IEC and ISO standards
  used in IMDRF jurisdictions (IMDRF/Standards WG/N15FINAL:2014)
IMDRF Activity (international standards)

Work item titled “Standards - Improving the quality of international medical device standards for regulatory use” was approved and two documents have been published.
- The purpose of this Work Item is to identify and explore possibilities to improve the process of developing international standards used for regulatory purpose.

Optimizing Standards for Regulatory Use (IMDRF/Standards WG/N51:2018)
- How to improve standards and standards developing processes for use in device review.
- Regulatory Authorities (RAs) should enter the process as early in the standard’s life cycle as possible.
- Optimized standards will
  (1) streamline the device review process
  (2) improve the efficiency of regulations
  (3) establish productive dialogue among RAs, manufacturers, clinicians and the public.
IMDRF Activity (international standards)

**Standards WG in IMDRF**

- IMDRF Standards Liaison Program Framework (IMDRF/Standards WG/N72:2022)
  - The internal IMDRF framework to establish and maintain the responsibilities associated with its liaison relationships within ISO and IEC Technical Committees.

- Relationships with IEC and ISO:
  - Category A Liaison status with IEC TC 62 and ISO TC 210
# International standards in Japanese regulation

Medical devices are regulated based on their characteristics and risks to users or patients.

<table>
<thead>
<tr>
<th>GHTF Classification</th>
<th>PMD Act classification</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Category</td>
</tr>
<tr>
<td>Class A</td>
<td>Extremely low risk e.g., X-ray film</td>
</tr>
<tr>
<td>Class B</td>
<td>Low risk e.g., MRI, digestive catheters</td>
</tr>
<tr>
<td>Class C</td>
<td>Medium risk e.g., dialyzer</td>
</tr>
<tr>
<td>Class D</td>
<td>High risk e.g., pacemaker</td>
</tr>
</tbody>
</table>

As of February 8, 2024.
Certification Criteria

◆ Certification criteria (Third party Certification)
The “certification criteria” are specified by the MHLW. Registered third-party certification bodies utilize the standards to confirm the conformity of Class II or III medical devices to the technical requirements.

※ Third-party certification bodies are required to comply with ISO/IEC 17021 and ISO/IEC 17065

1) Regarding Class II medical devices
⇒ 932 certification criteria have already developed.

2) Regarding Class III medical devices
Pharmaceutical Affairs Law was revised and enforced in November 2014
⇒ The scope of third party certification was expanded from class II to class III.
⇒ 12 certification criteria have already developed.
International standards in Japanese regulation

Example for Certification Criteria (Class II)

Certification criterion is consisted of Japanese industrial standard (JIS) and Purpose of use and effect.

Structure of certification criteria

<table>
<thead>
<tr>
<th>No.</th>
<th>Nomenclature of Applicable Medical Devices (JMDN)</th>
<th>Certification criterion</th>
<th>Purpose of use and effect</th>
</tr>
</thead>
</table>
| 1   | 1. X-ray system, diagnostic, general-purpose, mobile, analogue  
2. X-ray system, diagnostic, general-purpose, portable, analogue  
3. X-ray system, diagnostic, general-purpose, portable, digital  
4. X-ray system, diagnostic, general-purpose, stationary, analogue  
5. X-ray system, diagnostic, general-purpose, stationary, digital  
6. X-ray system, diagnostic, general-purpose, mobile, digital | T 0601-1-3  
Z 4751-2-54 | To provide the imaging information of human body for medical care used with the scintillation effect, photo-effect or ionization effect that X-ray went through a body has. |

JIS required by technical requirement

JIS T 0601-1-3 is based on IEC 60601-1-3:2008, Amd.1:2013 (IDT)  
JIS Z 4751-2-54 is based on IEC 60601-2-54:2009, Amd.1:2015 (IDT)
International standards in Japanese regulation

**Example for Essential Principles Checklist**

A checklist of conformity to the Essential Principles is basically published as notification.

<table>
<thead>
<tr>
<th>Essential Principles of Safety and Performance of Medical devices</th>
<th>Applicable</th>
<th>Method of Conformity</th>
<th>Identity of Specific Documents</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. General requirements</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Design) Clause 1 Medical devices should be designed and manufactured</td>
<td>Applicable</td>
<td>Show the conformity with recognized standard included requirements</td>
<td>Ordinance on Standards for Manufacturing Control and Quality Control of Medical Devices and In Vitro Diagnostic Reagents (MHLW Ministerial Ordinance No. 169 in 2004)</td>
</tr>
<tr>
<td>(Risk management) Clause 2 The solutions adopted by the manufacturer</td>
<td>Applicable</td>
<td>Show risk management is conducted according to recognized standard</td>
<td>JIS T 14971: &quot;Medical devices -- Application of risk management to medical devices&quot;</td>
</tr>
</tbody>
</table>

**Identity of Specific Documents**

MHLW Ministerial Ordinance No. 169 is based on ISO 13485:2016
JIS T 14971 is based on ISO 14971:2019 (IDT)

- JIS T 14971: "Medical devices -- Application of risk management to medical devices"
- JIS Z 4751-2-54:2012: "Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy"
International standards in Japanese regulation

**JIS standards required technical requirement in certification criteria (Class II)**

Based on WTO TBT agreement, JIS is basically harmonized with ISO and IEC standards where they exist.

⇒ More than half of these JIS are based on international standards.

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