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

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IMDRF International Medical Device Regulators Forum

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

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)

  <u>These standards are recognized by majority of IMDRF jurisdictions</u>
  - Good clinical practice ： ISO 14155:2011
  - Risk management： ISO 14971:2007
  - 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)

Standards WG in IMDRF

- 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.

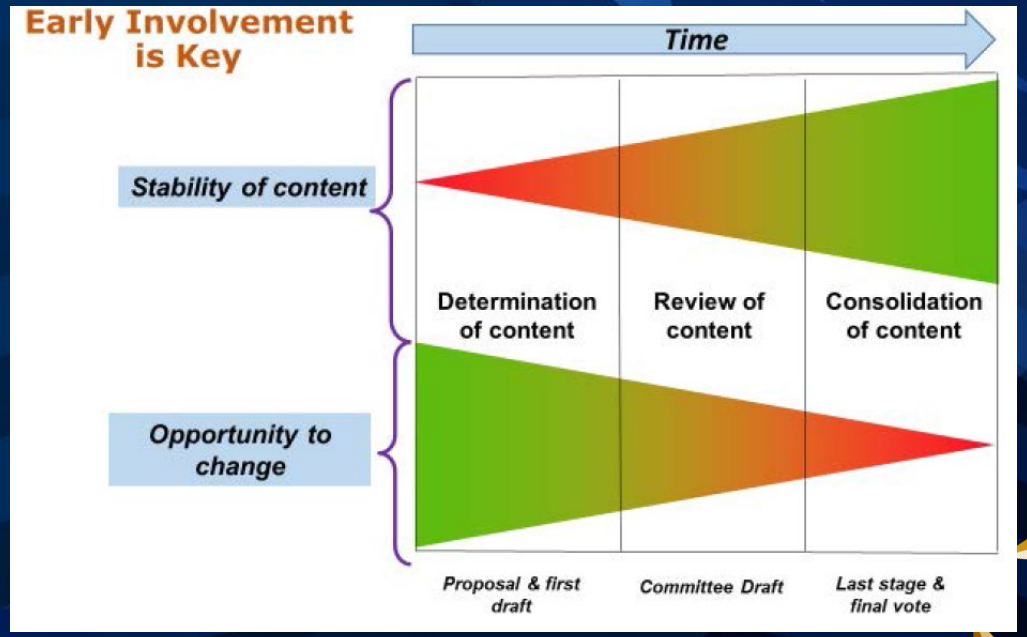
- Optimizing Standards for Regulatory Use (IMDRF/Standards WG/N51:2018)
  - How to improve standards and standards developing processes for use in device review.
  - Regulatory Authorities (RAs) should enter the process as early in the standard’s life cycle as possible.
  - Optimized standards will
    (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.

GHTF Classification		PMD Act classification		
		Category	Regulatory requirements	Japanese MD Nomenclature
Class A	Extremely low risk e.g., X-ray film	General MDs (Class I)	**Self declaration** Approval of the product is not required, but marketing notification is necessary.	1,225
Class B	Low risk e.g., MRI, digestive catheters	Controlled MDs (class II)	**Third party Certification** Certification by a registered certification body is required. ・Certification criteria	2,029 (1,523 for 3rd Party)
Class C	Medium risk e.g., dialyzer	Specially Controlled MDs (class III & IV)	**Minister's Approval (Review by PMDA)** The Minister's approval for the product is required. ・Approval criteria ・Review guideline	826 (44 for 3rd Party)
Class D	High risk e.g., pacemaker			375

As of February 8, 2024.

International standards in Japanese regulation

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.

As of February 8, 2024.

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**

No.	Nomenclature of Applicable Medical Devices (JMDN)	Certification *criterion*	
		JIS	Purpose of use and effect
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.

Essential Principles of Safety and Performance of Medical devices	Applicable	Method of Conformity	Identity of Specific Documents
1.General requirements			
(Design) Clause 1 Medical devices should be designed and manufactured ・・・・・・	Applicable	Show the conformity with recognized standard included requirements Show risk management is conducted according to recognized standard	Ordinance on Standards for Manufacturing Control and Quality Control of Medical Devices and *In Vitro* Diagnostic Reagents（MHLW Ministerial Ordinance No. 169 in 2004） JIS T 14971:「Medical devices -- Application of risk management to medical devices」
（Risk management） Clause 2 The solutions adopted by the manufacturer ・・・・・・	Applicable	Show risk management is conducted according to recognized standard	JIS T 14971:「Medical devices -- Application of risk management to medical devices」
			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
		to verify the effective	

Identity of Specific Documents

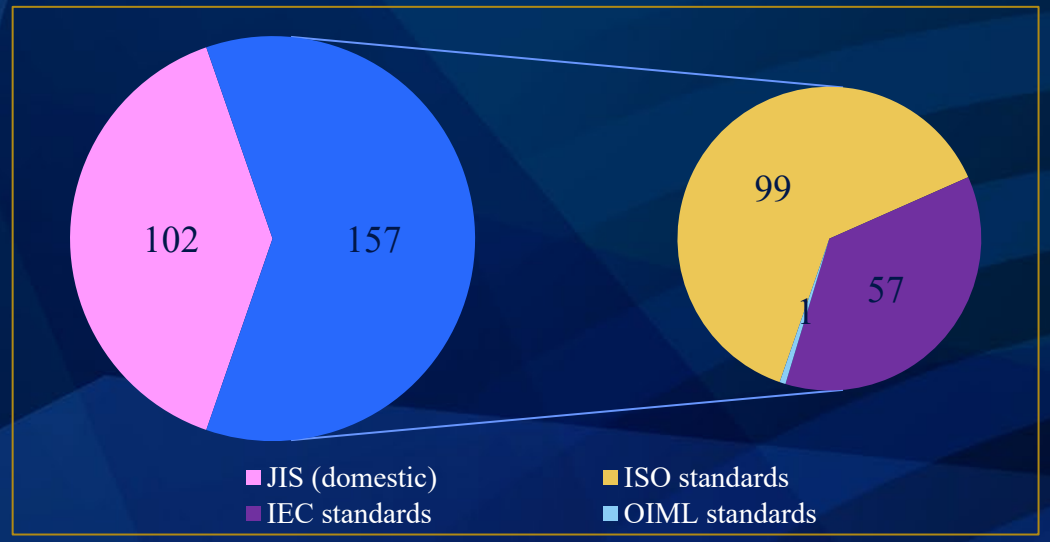
MHLW Ministerial Ordinance No. 169 is based on ISO 13485:2016
JIS T 14971 is based on ISO 14971:2019 (IDT)

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.



Imagawa Kuniki, Yoshiaki Mizukami, and Seiko Miyazaki. "Regulatory convergence of medical devices: a case study using ISO and IEC standards." Expert review of medical devices 15.7 (2018): 497-504.

IMDRF
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