



# International standardization activities for medical devices in Japan

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# Japan's Participation in ISO and IEC

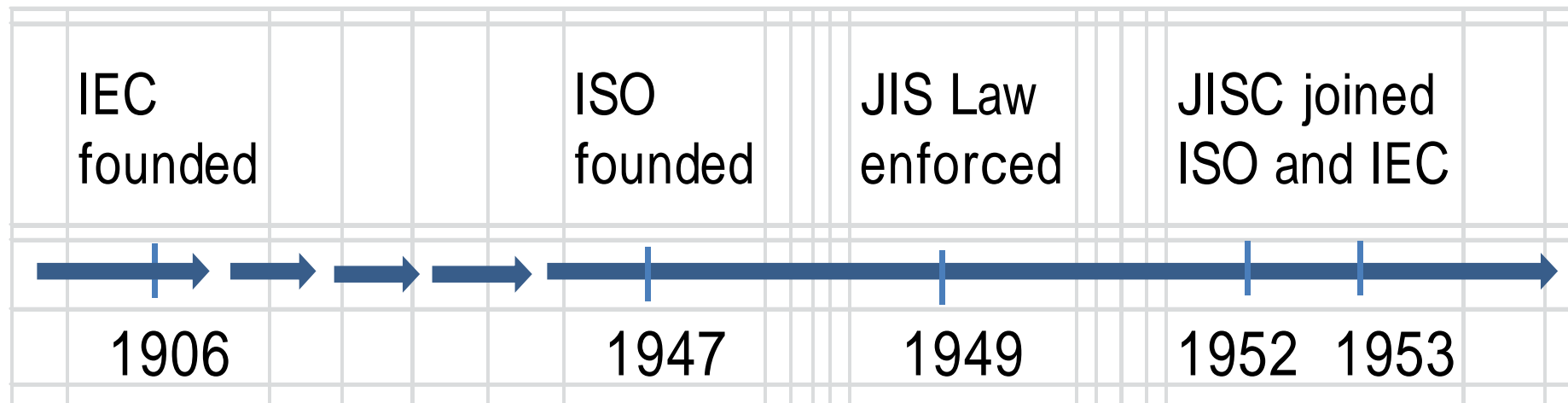
( ISO Statutes 3.2 )

Only one body in each country may be admitted to membership.

( IEC Statutes 4 )

There shall be only one National Committee for each country.

Countries	ISO	IEC
U.S.	ANSI	
UK	BSI	
Germany	DIN	DKE
France	AFNOR	UTE
Italy	UNI	CEI
Japan	JISC	



# Framework of Japan's Deliberations on ISO and IEC

JISC is a member body of both ISO and IEC following Cabinet approval in 1952.  
ISO and IEC have totally about 900 TCs and SCs, for which JISC outsources about 300 related parties in industry, academia and so on.

International Organization for Standardization (ISO)  
737 TCs and SCs  
(Japanese secretariats: 67)

International Electrotechnical Commission (IEC)  
184 TCs and SCs  
(Japanese secretariats: 23)

(As of December 31, 2012)



Japanese Industrial Standards Committee (JISC)



Secretariat

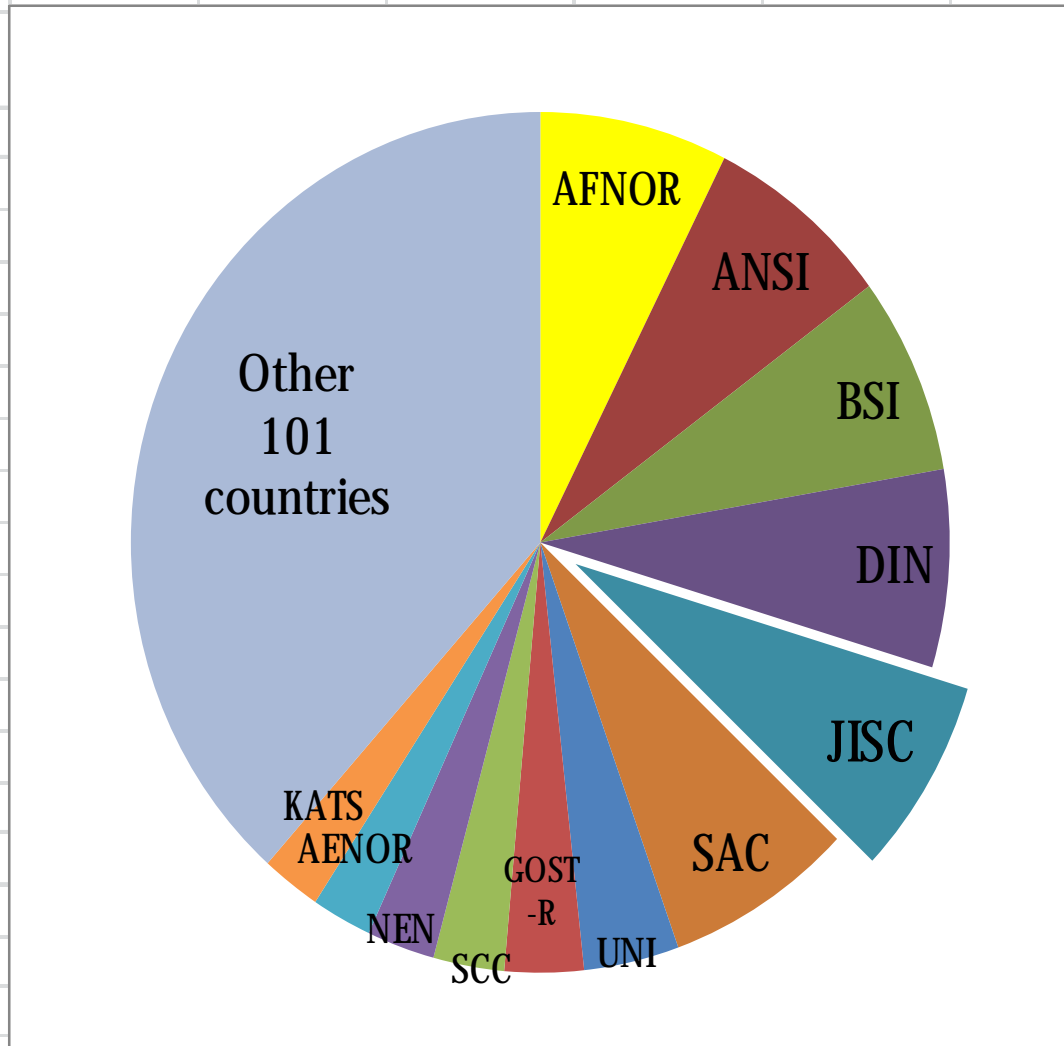


Outsource

**METI**  
Technical regulations, standards and conformity assessment unit

National Mirror Committees  
About 300 related parties in industry, academia and so on.

# Financial Contribution to ISO



ISO subscription fees in 2104

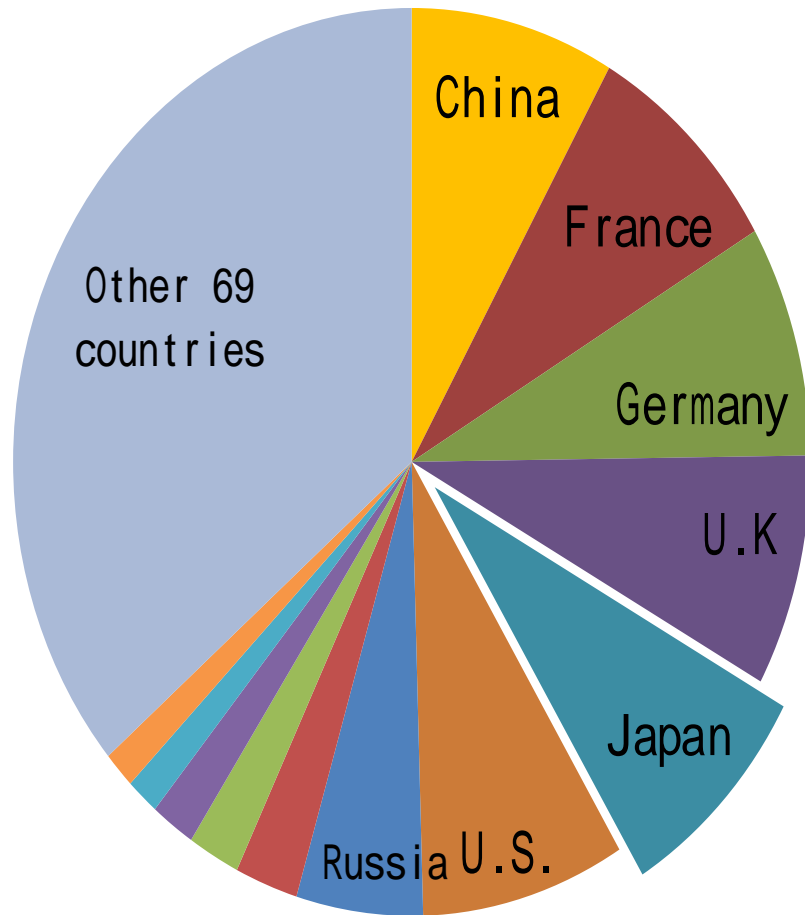
Member Body	Unit
AFNOR (France)	286
ANSI (U.S.)	286
BSI (UK)	286
DIN (Germany)	286
JISC (Japan)	286
SAC (China)	286
UNI (Italy)	145
GOSTR (Russia)	120
SCC (Canada)	108
NEN (Netherlands)	103
AENOR (Spain)	92
KATS (South Korea)	90
Other 101 countries	1480
<b>Total 123 countries</b>	<b>3854</b>

1 unit = 5355 CHF 1 CHF = 86 yen

Japan:  $286 \times 5355 \times 86 = 130$  million yen

(As of July 2013)

# Financial Contribution to IEC



IEC subscription fees in 2013

Country	CHF
China	780,200
France	780,200
Germany	780,200
Japan	780,200
UK	780,200
U.S.	780,200
Russia	485,300
Italy	241,400
Canada	199,700
Spain	169,900
Brazil	126,000
Netherlands	124,200
Other 69 countries	3,422,200
<b>Total 81 countries</b>	<b>9,449,900</b>

1 CHF = 86 yen

Japan: 780,200 × 86 = 67 million yen

(As of May 2013)

# Management Structure of ISO and IEC

International Organization for Standardization (ISO)



General Assembly (annually)

Council (semi-yearly, 20 countries)

Technical Management Board (TMB)  
14 countries

Technical Committee (TC) 224 TCs

Subcommittee (SC) 513 SCs

Working Groups (WG) 2544 WGs



International Electrotechnical Commission (IEC)

Council (annually)

Council Board (CB, 15 countries)

Strategic Management Board (SMB)  
15 countries

Joint Technical Committee (JTC 1: Information)

Subcommittee (SC) 17 SCs

Working Groups (WG) 89 WGs

Technical Committee (TC) 96 TCs

Subcommittee (SC) 79 SCs

Working Groups (WG) 458 WGs

(As of January 1, 2012)

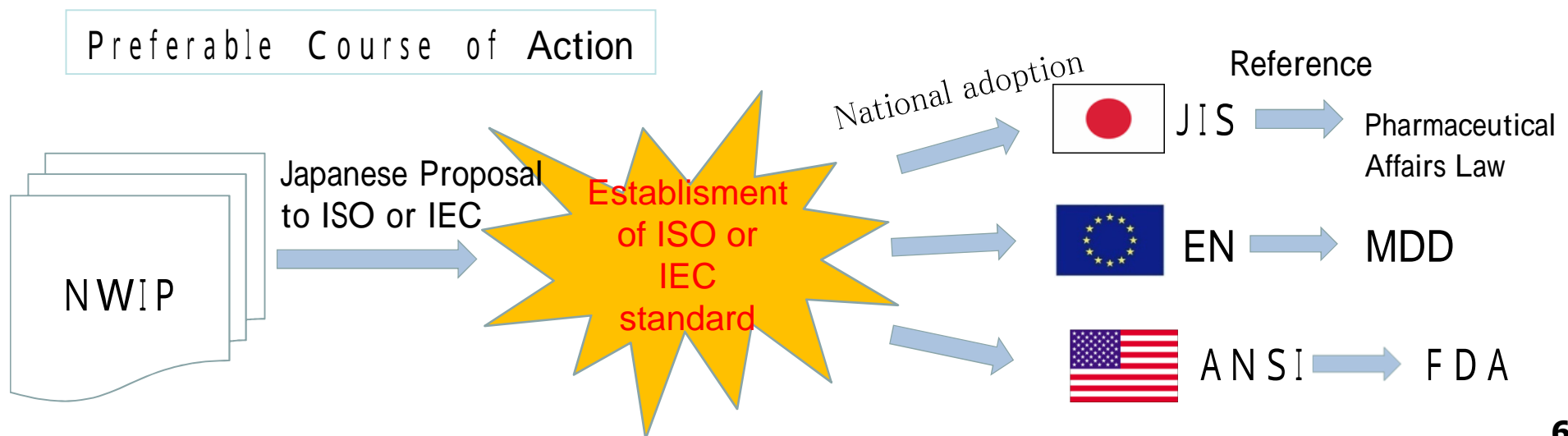
# Relationship between JISs and International Standards

Source: JISC Medical Devices Safety WG (interim report)

- Alignment of JISs with ISOs and IECs in accordance with WTO/TBT  
Where international standards exist or their completion is imminent, JISC shall use them or the relevant part of them, as a basis for the standard it develops, except...

## Preferable Course of Action (below)

This action would be a NWIP(New Work Item Proposal) to ISO or IEC, followed by establishment of an ISO or IEC standard, which will lead to the adoption of the standard as a national standard in most countries, and be referenced in technical regulations as the basis for the regulations regarding medical devices in question.



# Characteristics of JISs in Medical Devices

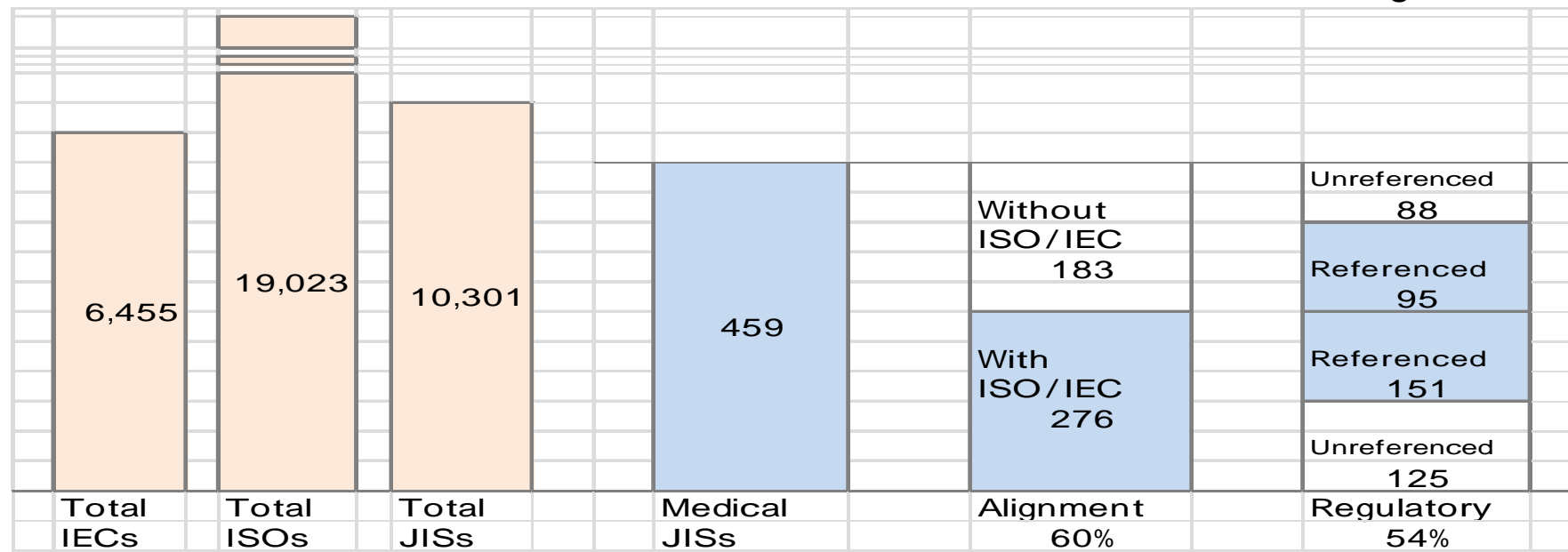
Source: JISC Medical Devices Safety WG (interim report)

## Close alignment with ISO and IEC

More than 60% of JISs for medical devices come from ISO or IEC standards.

## Frequent use in regulatory framework

More than 50% of JISs for medical devices are referenced in technical regulations



## Close collaboration with MHLW

More than 90 % of JISs for medical devices are established by MHLW or MHLW/METI





# Characteristics of ISO and IEC Standards in Medical Devices

Source: JISC Medical Devices Safety WG (interim report)

## Many bestselling standards

ISO and IEC standards for medical Devices are only 4% of the total standards. However they include many bestselling standards such as the following.

ISO 13485 (medical devices -- quality management systems – requirements for regulatory purposes)      JIS Q13485

ISO 14971 (medical devices -- application of risk management to medical devices)  
JIS T14971

IEC 60601-1 (medical electrical equipment - Part 1: general requirements for basic safety and essential performance)      JIS T0601-1

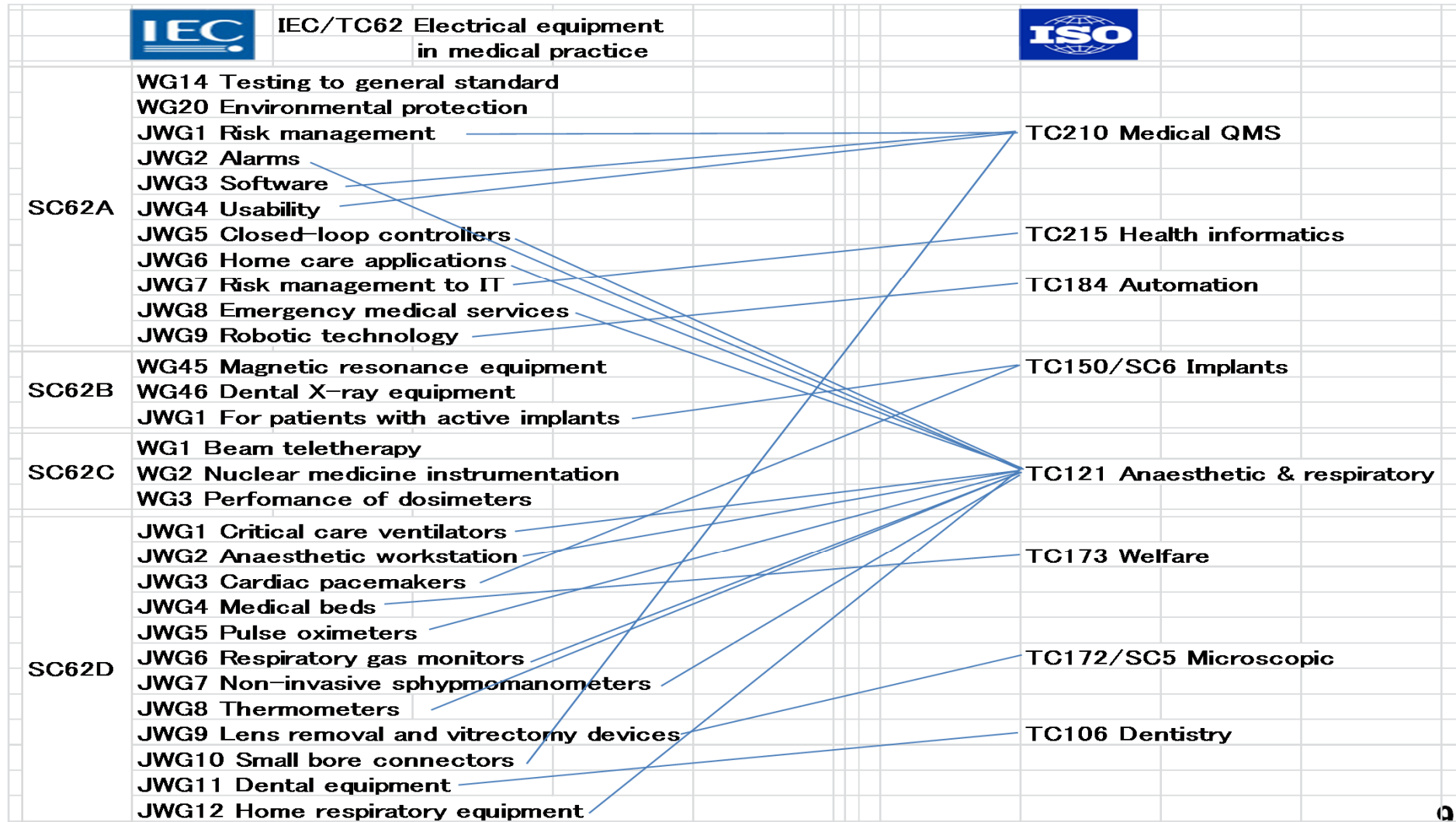
IEC 62304 (medical device software - software life cycle processes)      JIS T2304

# Characteristics of ISO and IEC Standards in Medical Devices

Source: JISC Medical Devices Safety WG (interim report)

## Frequent formation of JVGs

ISO and IEC have close relationship to especially develop small medical devices.



# Strategic International Standardization Projects for Medical Devices

Projects	Outsourcing companies	Relevant TCs
International standardization for measurement validity of medical devices using reference materials	Japan Microarray Consortium, AIST	ISO/TC212(clinical laboratories testing)
International standardization for High Intensity Therapeutic Ultrasound (HITU)	Tokyo Women's Medical University, Tohoku University	IEC/SC 62D (electromedical devices)
International standardization for medical plasma equipment	AIST, Nikon Corporation, Tokyo University	
International standardization for photo-dynamic therapy	Tokyo Women's Medical University, Panasonic Healthcare Co., Ltd.	
International standardization for real time controlled radiometry systems	Hokkaido University	IEC/SC 62C (equipment for radiotherapy)
International standardization for serum panels and pre-measurement process	JCCLS	ISO/T212 (clinical laboratories testing)
International standardization for dental materials and devices	JRCDP	ISO/TC106 (dentistry)
International standardization for preparation procedure of thin condoms testing	The Japan Rubber Manufacturers Association	ISO/TC157 (non-systemic contraceptives and STI barrier prophylactics)
International standardization for conical connectors of respiratory systems	Japan Association of Medical Devices Industries	ISO/TC121 (anaesthetic and respiratory equipment)
International standardization for medical waveform format encoding rules	Medical Information System Development Center	ISO/TC215 (health informatics)

## Strategic International Standardization Projects for Medical Devices

Projects	Outsourcing companies	Relevant TCs
International standardization for basic technology of regenerative cell medicine	FIRM	ISO/TC276 (biotechnology)
International standardization for evaluation of bioceramics	JFCA	IISO/TC150 (implants)
International standardization for model bones	Tohoku University	
International standardization for medical equipment and products of traditional medicine	The Japan Liaison of Oriental Medicine	ISO/TC 249 (traditional Chinese medicine)

## Summary

1. JISC is the secretariat of JISs and a member body of both ISO and IEC.
2. JISC established a Medical safety WG and reported on strategic standardization plan in order to promote international standardization in the field of medical devices.

<https://www.jisc.go.jp/newstopics/2013/201301iryoyouguwg.htm>

- Alignment of JISs with ISOs and IECs
  - Preferable course of action
  - Response to the JWGs between ISO and IEC
  - Promotion of Involvement of medical manufactures and PMDA in standardization process
3. METI has funded 14 projects concerning medical devices to propose NPs to ISO or IEC

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