Medical Device Regulations and Utilization of International Standards in Japan

Katsuhisa Ide

Div. of Standard for Medical Devices

Office of Standards and Guidelines Development

Pharmaceuticals and Medical Devices Agency

Agenda

- Overview of Risk-based Medical Device Regulations in Japan
- Process of Developing Standards in Japan
- Utilization of Standards

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GHTF Classification and Medical Device Category

Regulations on medical device, based on risk

GHTF Classification	
Class A	extremely low risk X-Ray film
Class B	low risk MRI, digestive catheters
Class C	medium risk artificial bones, dialyzer
Class D	high risk pacemaker, artificial heart valves

Medical Device Category in Japan	
Class I	**General MDs** X-Ray film
Class II	**Controlled MDs** MRI, digestive catheters
Class III	**Specially Controlled MDs** artificial bones, dialyzer
Class IV	**Specially Controlled MDs** pacemaker, artificial heart valves

Risk based classification

N77 Principles of Medical Devices Classification

GHTF（Global Harmonization Task Force)
Guidance and Japanese Regulation (Relationship)

GHTF

- **SG1 Definition**
  Risk base classification（N77）
  Essential Principle(EP)（N68）
  STED（N11）
- **SG2 AE Reporting**
  Field Safety Notice
- **SG3 Auditing**
- **SG4 QMS**
- **SG5 Clinical Investigation**

Japan (PMD-Act)

- **Definition**
  Risk base classification
  Essential Principle
  STED
- **GVP Ordinance**
  AE Reporting
  Field Safety Notice
- **Auditing**
- **QMS Ordinance**
- **Notifications on Clinical Investigation**

JMDN
Japanese Medical Device Nomenclature

- Based on GMDN 2003

  (GMDN: Global Medical Device Nomenclature)
- Implemented in 2005
- Not updated simultaneously with current GMDN
- MHLW creates new JMDN referring to current GMDN, when a medical device which doesn't meet any of existing JMDN is approved

Risk Based Classification and Regulation

As of January, 2016

Medical Device Classification in Japan		
Category	**Pre-market regulation**	**# of JMDN***
General MDs (Class I)	**Self Declaration**	**1,195**
Controlled MDs (class II)	**Third party Certification**	**1,972**
Specially Controlled MDs (class III & IV)	**Minister's Approval (Review by PMDA)**	**771**
		350

*JMDN: Japanese Medical Device Nomenclature

Resource Allocation
depending on potential risk

Class I MD

Self Declaration (submit Marketing Notification to PMDA)

Class II & Class III MD with Certification Standard

Certification by Registered Certification Body (RCB)

Class III/IV

Approval by MHLW (reviewed by PMDA)

MHLW/PMDA can Focus on the thorough review of higher-risk/innovative Medical Devices

Certification

RCBs review Class II & Class III MD with Certification Standard

RCB:

- Gives certification for marketing to the applicant
- Not “Accredited Body for ISO certificate”
- Registered by MHLW
- Assessed by PMDA
- Conducts review with Certification Standards (CS)

Products out of scope of CS or not comply with CS should go to Minister’s Approval process

Certification Standards (CS)

- Associated with JMDN
- Essential Principle Check List with relevant standards is attached to each Certification Standard

Structure

1. Scope

   Applicable JMDN to the CS is listed

2. Technical Standard

   Japanese Industrial Standard (JIS) (in most case) which the product must comply with

3. Indication for Use

   Based on the definition of applicable JMDN

Japanese Industrial Standard (JIS)

JIS：

Japanese Technical Standard based on International Standards or other recognized standards which is *used internationally.*

If there is no such international standards to refer, then alternatively using Guidance Documents which National Competent Authorities (NCA）issues or Industry Standard such as NEMA* Standard etc.

* National Electrical Manufacturers Association (USA)

Example of Certification Standard
Essential Principles Checklist

Ministerial Notification No. 112, Appendix Table, No.3-1
Essential Principles Checklist (The standard for X-ray system, diagnostic, general-purpose, mobile, analogue etc)

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」
		:	
(Effective for medical devices) Clause 6 All known and foreseeable risks, and ・・・・・・	Applicable	verify the effective to conduct risk analysis. Show the conformity with recognized Standard to verify the effective	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 203.6.3.2.101 , 203.6.3.2.102, 203.6.4.3.104.3, 203.6.4.3.104.4～5and/or6 203.6.4.7.

Example of Certification Standard
Essential Principles Checklist

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Identity of Specific Documents

MHLW Ministerial Ordinance No. 169 is based on ISO 13485：2003

JIS T 14971 is based on ISO 14971:2007 (IDT)

Example of Certification Standard
Essential Principles Checklist

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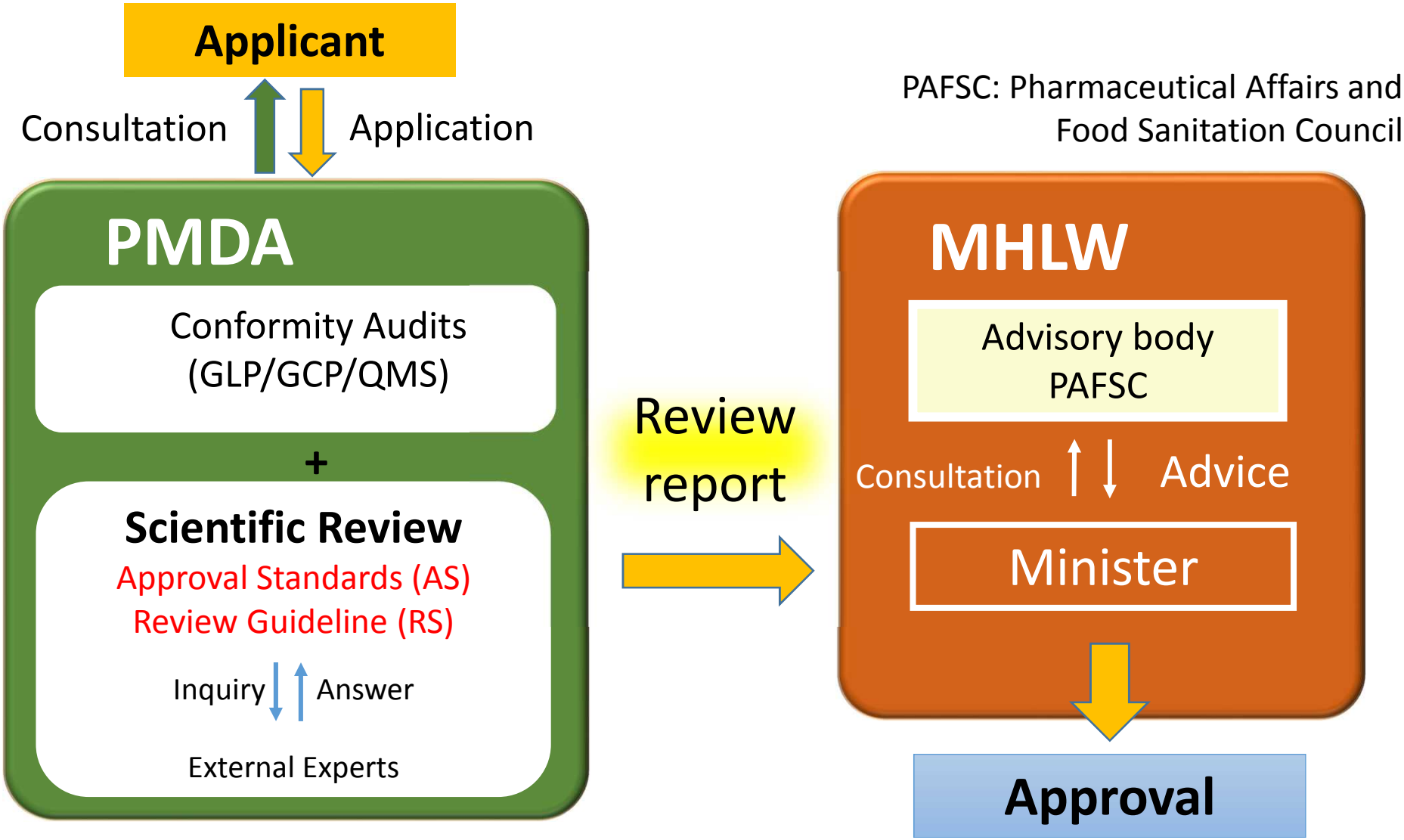
Identity of Specific Documents

JIS Z 4751-2-54:2012 is based on IEC 60601-2-54:2009 (MOD)

Approval

PMDA reviews Class III/IV MDs



JMDN and CS/AS and RG

As of 2016 Mar

	JMDN	Number of TS or Review Guideline(RG)	JMDN Covered %
Category I	1195	NA	NA
Category II	1972	936 CS（1519 JMDN)	77
Category III	771	10 CS（39 JMDN) 8 RG（32 JMDN）	14
Category IV	350	43 AS（89 JMDN）	
Total	4288	996 (1679 JMDN)	

CS: Certification Standard
AS: Approval Standard
RG: Review Guidance

Agenda

- Overview of Risk-based Medical Device Regulations in Japan
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- Utilization of Standards

Standards and Guidance setting in PMDA

Office of Standards and Guidelines Development

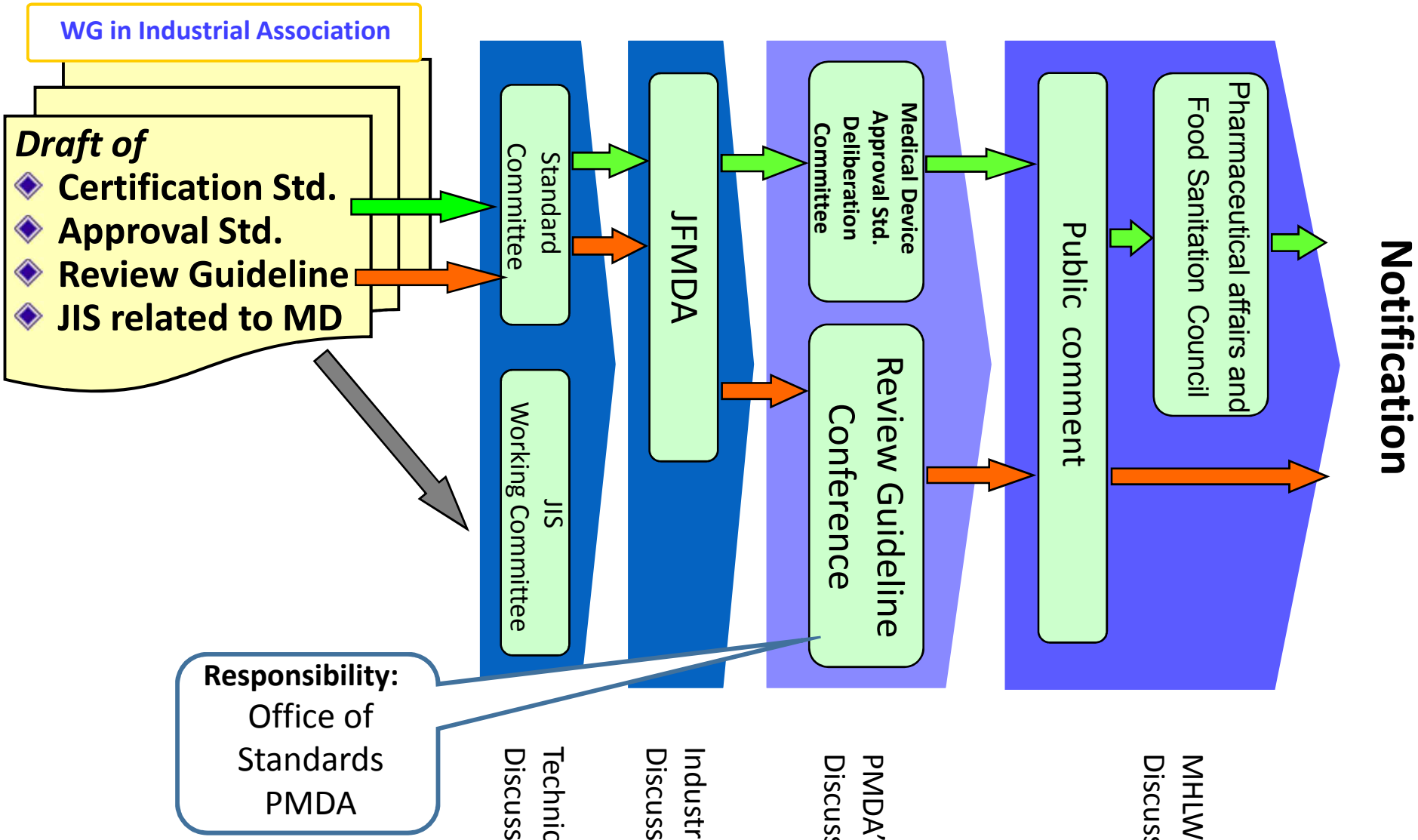
Division of Pharmacopoeia and Standards for Drugs

- Secretariat of Japanese Pharmacopoeia Expert committees
- Registration of Master Files for Drug Substances

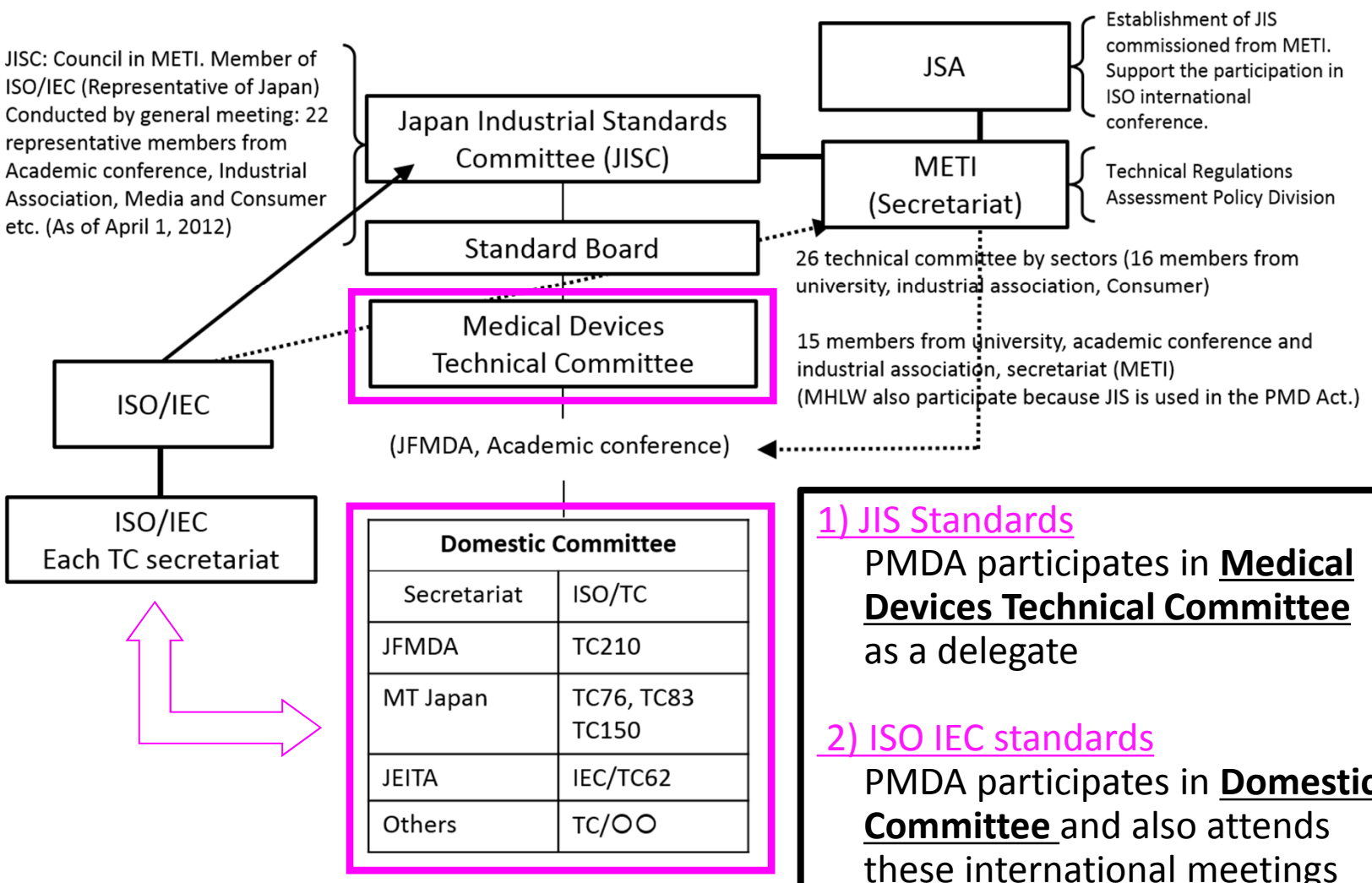
Division of Standards for Medical Devices

- Secretariat of Committees for Certification and Approval Standards
- Cooperation to setting of JIS, ISO and IEC standards
- Openness these standards to the public in a timely manner.

Making Process of AS/CS/RG



Involvement in JIS, ISO and IEC Standards Development



1) JIS Standards

PMDA participates in **Medical Devices Technical Committee** as a delegate

2) ISO IEC standards

PMDA participates in **Domestic Committee** and also attends these international meetings

PMDA's Involvement in ISO/IEC TC

◆ PMDA is involved to/participate **Standard Technical Committee**

ISO/TC 210	Quality management and corresponding general aspects for medical devices
ISO/TC 194	Biological and clinical evaluation of medical devices
IEC/TC 62	Electrical equipment in medical practice
ISO/TC 215	Health informatics
ISO/TC 106	Dentistry
ISO/TC 229	Nanotechnologies
ISO/TC 276	Biotechnology
ISO/TC 172	Optics and photonics
ISO/TC 121	Anaesthetic and respiratory equipment
ISO/TC 150	Implants for surgery

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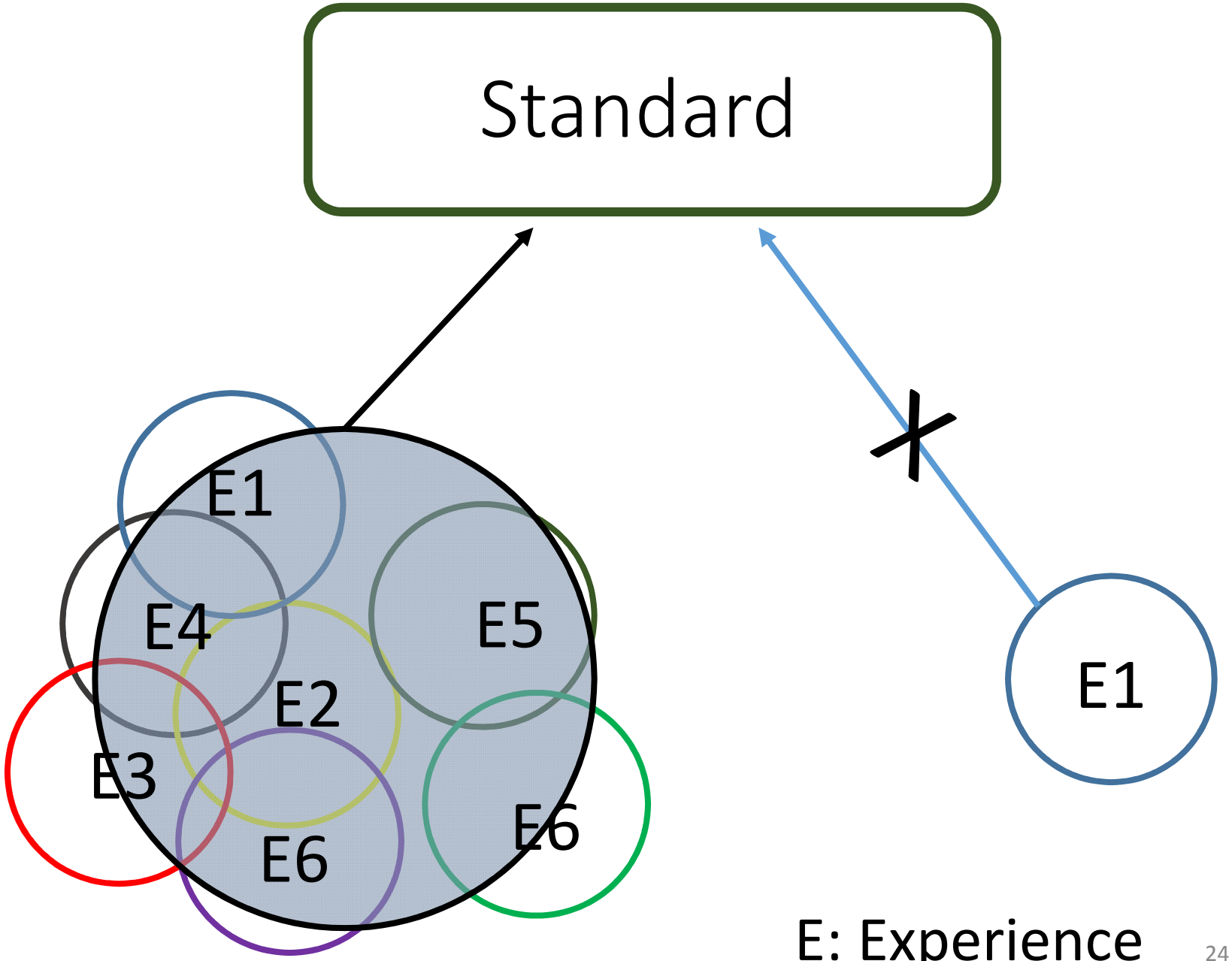
What is “Standard”?

GHTF/SG1/N44: 2008

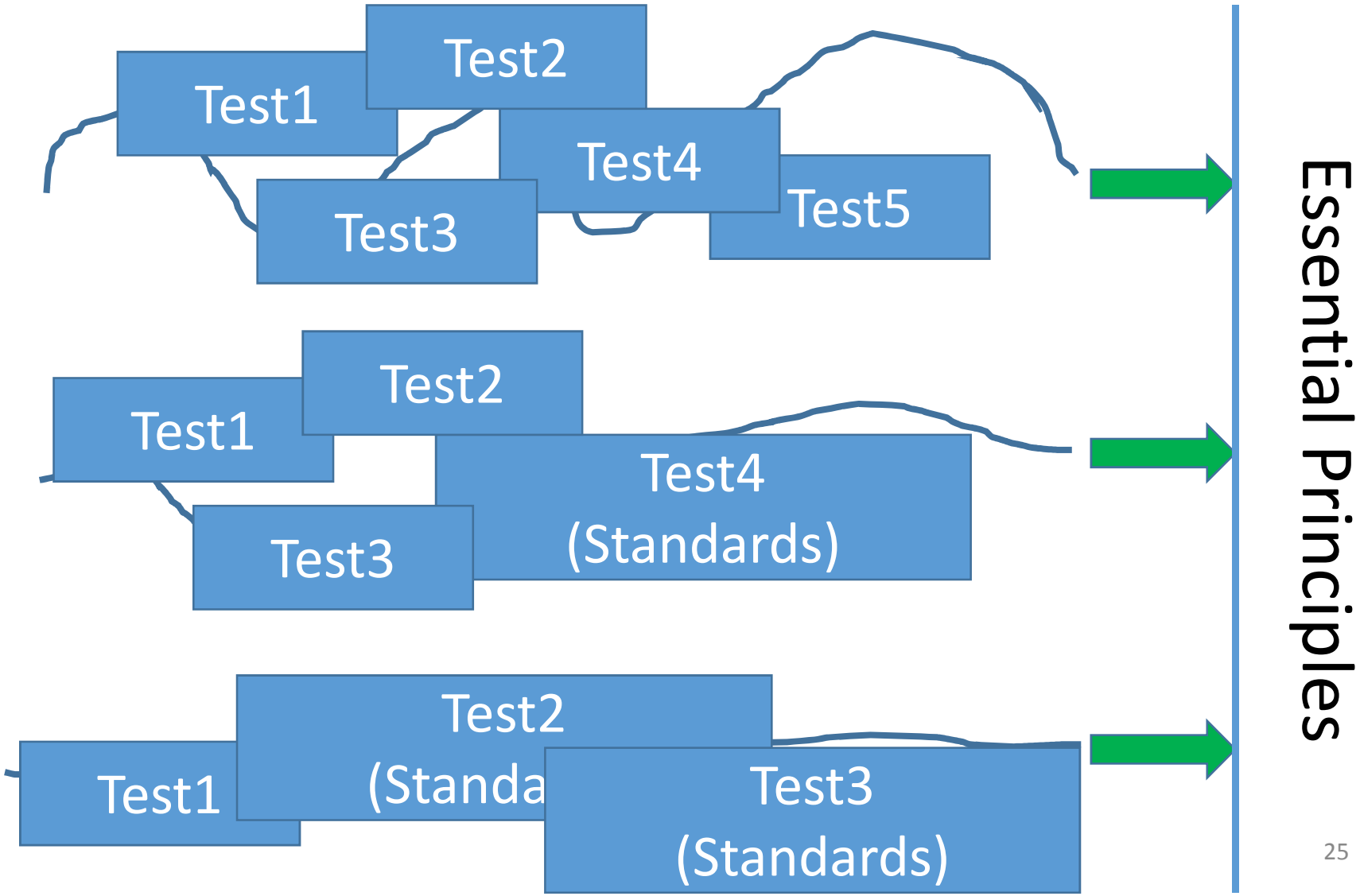
Standard: Document, established by consensus and approved by a recognised body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.

NOTE: **Standards should be based on the consolidated results of science, technology and experience**, and aimed at the promotion of optimum community benefits. (ISO/IEC Guide2:2004, definition 3.2)

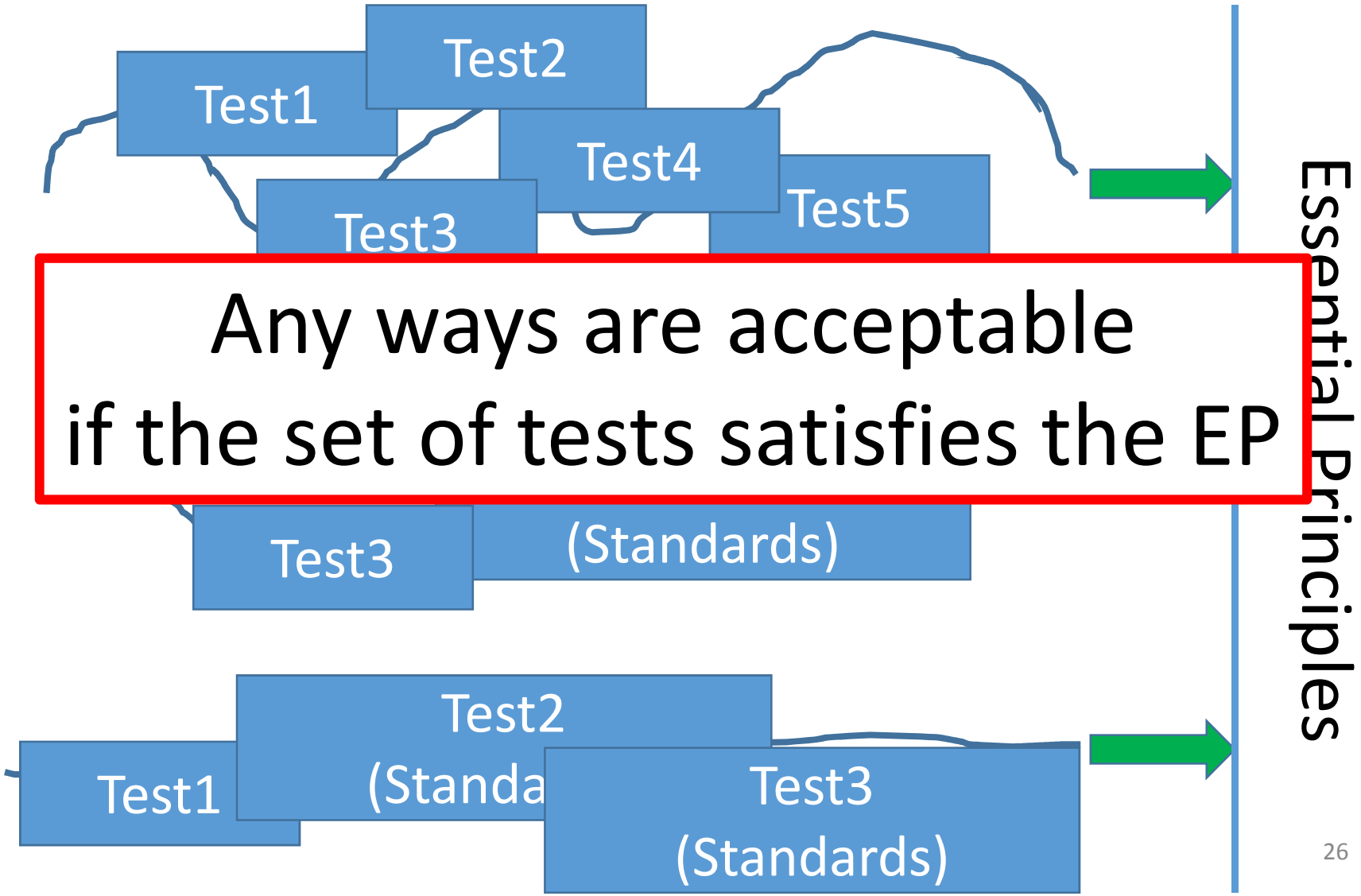


E: Experience

Demonstrating Conformity Assessment



Demonstrating Conformity Assessment



GHTF/SG1/N44: 2008

2.2 Purpose

To:

- encourage and support the development of international consensus standards for medical devices that may serve to demonstrate conformity with the Essential Principles of Safety and Performance of Medical Devices (hereafter referred to as 'Essential Principles');
- encourage manufacturers to conform with appropriate international standards;
- persuade Regulatory Authorities to introduce a mechanism for recognising standards that provide manufacturers with a method of demonstrating conformity with the GHTF harmonized Essential Principles;
- support the concept that **in general, the use of standards is voluntary and manufacturers have the option to select alternative solutions to demonstrate their medical device meets the relevant Essential Principles.**

Utilization of International Standard

Utilization of international Standards under the same concept and in the same assessment,

Can make win-win situation for both Industries and regulators

- ***Reduce duplication***
- ***Enhance Transparency***
- ***Save preparing time/cost***
- ***Reduce review time***
- ***Enhance Safety and Efficacy***

DHANYAVAD!!

URL http://www.pmda.go.jp

http://www.std.pmda.go.jp/stdDB/index_e.html

Medical Devices Regulations and Capacity Building

Dr. S. Eswara Reddy

Joint Drugs Controller (India), CDSCO (HQ)

18th May , 2016

Outline:

- Introduction
- Definitions
- Notified Devices
- Related Rules/Schedules
- Concerns with present regulations
- Proposed Regulations
- Conclusion

Introduction

Medical Devices:

- Market Size: Rs 40, 000 Cr ($ 6.5 US Billion)
- Around 350 Licenses
- Only Notified devices are regulated
- Regulated as Drugs
- Mostly Imports
- Dynamic in nature
- 100% FDI
- Medical Technology to Rural and Semi-rural population

Introduction contd...

Medical Technologies/Devices:

1. Medical Equipments/Instruments

   Eg. CT Scan, MRI, X-Ray machines etc

2. Medical Implants

   Eg. Cardiac Stents, IOL, Orthopedic Implants

3. Medical Disposables

   Eg. Syringes, Needles, Catheters

4. Medical Furniture

   Eg. Hospital Beds, Wheel Chair etc.

Medical Device Industry

Strength:

- Potentially huge market with growing urban middle class population
- Growing private hospitals aiming to attract Health Tourism
- Success of pharma and other paramedical areas
- Increasing healthcare expenditure

Opportunities:

- Overseas companies investing in India to set up R&D units
- Increasing Joint ventures & Overseas aid assisted projects
- Development of medical devices parks
  - Common Testing Facilities
  - Infrastructure
  - Developing at strategic locations

Drugs and Cosmetics Act and Rules

Definition

- Medical Devices and Diagnostics are considered as "Drugs"

- Section 3 (b) (iv)

  "Such devices intended for **Internal or external** use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by **notification** after consultation with the Board"

History of MD Regulations:

Definition	1983
Initially 3 devices are notified as Drugs	March,1989
Schedule M-III	Feb, 1994
The Second notification (IVD)	August, 2002
The Third notification	October, 2005
The fourth notification	January, 2016

The Govt of India has notified…

S. No	Name of the device	SLA/CLAA	Date of notification
1	Disposable Hypodermic Syringes	SLA	17-03-1989
2	Disposable Hypodermic Needles	SLA	17-03-1989
3	Disposable Perfusion Sets	SLA	17-03-1989
4	In vitro Diagnostic Devices for HIV, HbsAg and HCV and blood grouping sera	SLA	27-08-2002
5	Cardiac Stents	CLAA	06-10-2005
6	Drug Eluting Stents	CLAA	06-10-2005
7	Catheters	CLAA	06-10-2005
8	Intra Ocular Lenses	CLAA	06-10-2005
9	I.V. Cannulae	CLAA	06-10-2005
10	Bone Cements	CLAA	06-10-2005
11	Heart Valves	CLAA	06-10-2005
12	Scalp Vein Set	CLAA	06-10-2005
13	Orthopedic Implants	CLAA	06-10-2005
14	Internal Prosthetic Replacements	CLAA	06-10-2005
15	Ablation Devices	*CLAA	25-01-2016

In-Vitro Diagnostic Kits/reagents

- Notified Kits
  - Eg. HIV, HbsAg, HCV
  - Requires manufacturing License
  - For Import – Both Registration Certificate and import license.
- Non-Notified Kits
  - Eg. Testing kits for Malaria, TB, Cancer, etc.
  - Requires Manufacturing License
  - For Import- Only Import License

MD that are not notified, but regulated as Drug

- Condoms
- Intra Uterine Devices -Cupper T
- Vaginal Tubal Rings
- Blood bags
- Sutures and Ligatures
- Blood Grouping Sera
- Surgical Dressing
- Umbilical Tapes

Specific Rules and Schedules to MD & IVD

- Rule 109-A Labeling of Medical Devices
- Rule 125-A Standards for Medical Devices
- **Schedule M III** GMP Requirements
- Schedule R Standard for Mechanical Contraceptives
- Schedule R1 Standards for Medical Devices
- Schedule DII Annexure B - IVD

Inadequacies of regulatory systems

- Devices regulated as “drugs”
- Many provisions of D&C Act and Rules not appropriate for devices
- Regulations not harmonized with international practices
- Absence of risk based classification
- Lack of standards for QMS, Clinical Investigation, performance evaluation

Initiatives taken

- Developed MD specific guidelines for import and manufacturing.
- Constituted Subject Expert Committees
- Imparted training to Drugs Inspectors of CDSCO and State Inspectors on MD
- FAQ are posted on CDSCO website
- New set of Rules are being finalized for medical devices under D&C Act.
- Introduced Materiovigillance program
- Regular interaction with Industry/ Associations

Proposed Regulatory framework for medical devices

Medical Device Bill, 2016 is being drafted

- Medical Devices (Regulation) Bill
- New Definitions for - Medical Device, Manufacture, Clinical Investigation, Substantial Equivalence, Predicate device
- Clinical Investigation Requirements
- Designated MD Testing Centers
- "Medical Device Officer" in place of "DI"
- Medical Devices Technical Advisory Board.
- Classification of Medical Devices based on risk
- Standards for Medical Devices
- Role of Notified Bodies and Penal Provisions

MEDICAL DEVICES

- Instruments
- Apparatus
- Implants
- Machines
- Appliances
- Software
- Materials
- Related articles

which doesn't achieve its primary intended action in or on the human / animal body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means

- Diagnosis
- Prevention
- Monitoring
- Treatment
- Alleviation

} disease / injury

- Investigation, replacement, modification, or support of the anatomy or of a physiological process
- Supporting or sustaining life
- Control of conception
- Disinfection of medical devices

Medical Device Def: Cont....

(ii) an accessory to such an instrument, apparatus, appliance, material or other article;

(iii) a device which is reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system whether used alone or in combination intended to be used for examination and providing information for medical or diagnostic purposes by means of *in vitro* examination of specimens derived from the human body or animals.

Salient features of proposed Regulation for India under Rules

1. Separate set of Rules for medical devices for Import, Manufacture, Clinical Investigation and Sale
2. Risk Based classification
3. Notification of additional medical devices
4. Authorities to regulate medical devices
5. Standards for medical devices
6. No renewal of licence
7. Essential Principles of Safety and Performance of Medical Devices
8. Registration & Regulation of Notified Bodies
9. Use of IT enabled services

Classification in other countries

Risk Criteria	India (Proposed)	USFDA	EU	Japan	Singapore	IMDRF
Low	Class A	I	I	I	A	A
Low-Moderate	Class B	II	IIa	II	B	B
Moderate-High	Class C	III	IIb	III	C	C
High	Class D		III	IV	D	D

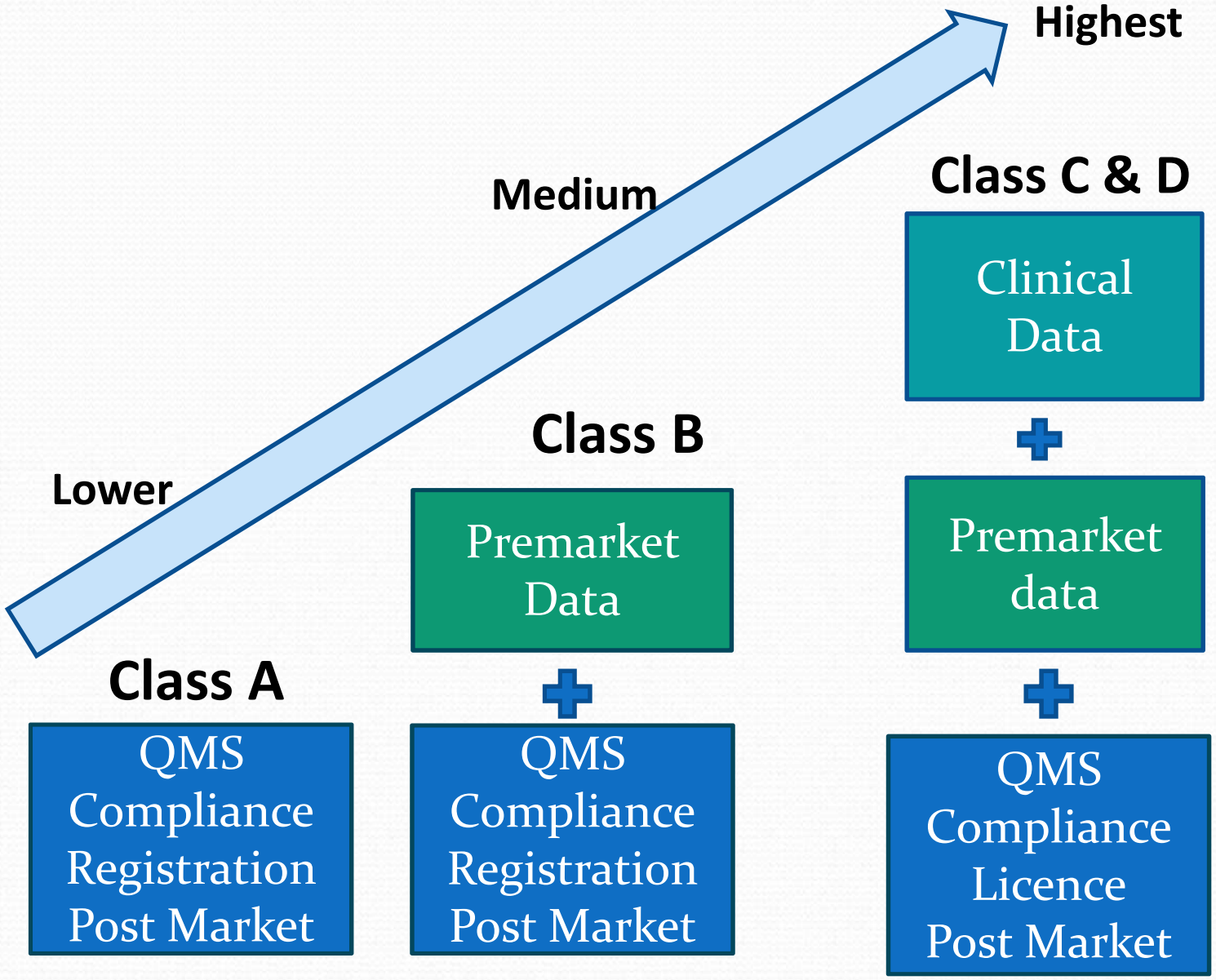
Global Risk Criteria for Classification

Category	Risk Involved	Explanation
Class A	Low	Malfunctioning of which may Cause negligible risk to the patient/user.
Class B	Low-Moderate	Malfunctioning of which may cause temporary injury to patients/user.
Class C	Moderate-High	Malfunctioning of which may cause permanent injury to patients/user.
Class D	High	Malfunctioning of which may cause permanent injury amounting to grievous hurt or death to patient/user.
Malfunctioning may lead to wrong diagnosis, injury/disability/death, under performance, which depends on the severity of harm caused by device.		

Proposed Classification

Risk Criteria	India (Proposed)	IMDRF	Regulatory Authority
Low	Class A	Class A	Notified Body*
Low-Moderate	Class B	Class B	Notified Body*
Moderate-High	Class C	Class C	CDSCO
High	Class D	Class D	CDSCO
* Electronic online system – Random Selection			

Regulatory scrutiny increases with Risk



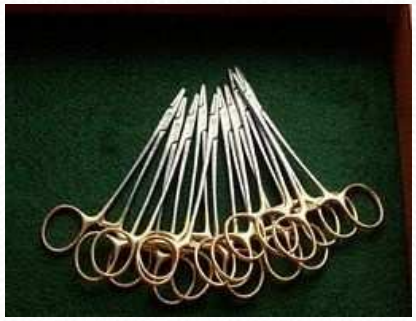
Low Risk
sterile & non
sterile

CLASS – A

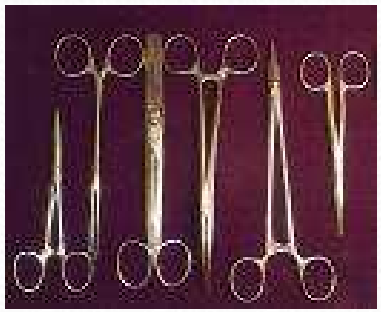






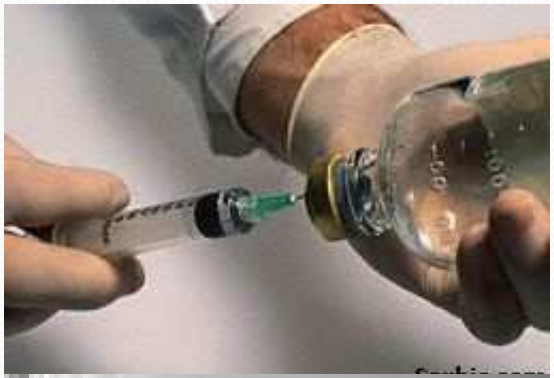







Controls for Class A devices

- Online application to CDSCO for registration of site and product
- Automatic transmission to a randomly selected Notified Body in case of domestic manufacturer and in case of imports CDSCO to take a call about in-house or external assessment.
- Compliance with QMS (Schedule M-III) to be verified by Notified Body within 30 days
- Non conformance- rectification by manufacturer
- Re-assessment by Notified Body
- Automatic registration of Manufacturing site/product by CDSCO where recommended by Notified body.
- Electronic generation of Registration Certificate
- Post market surveillance.
- Existing manufacturer to be registered within one year from date of enactment of these rules.
- **Clinical Trial/investigation, Animal testing, and Biocompatibility data not required.**



Low-Moderate Risk

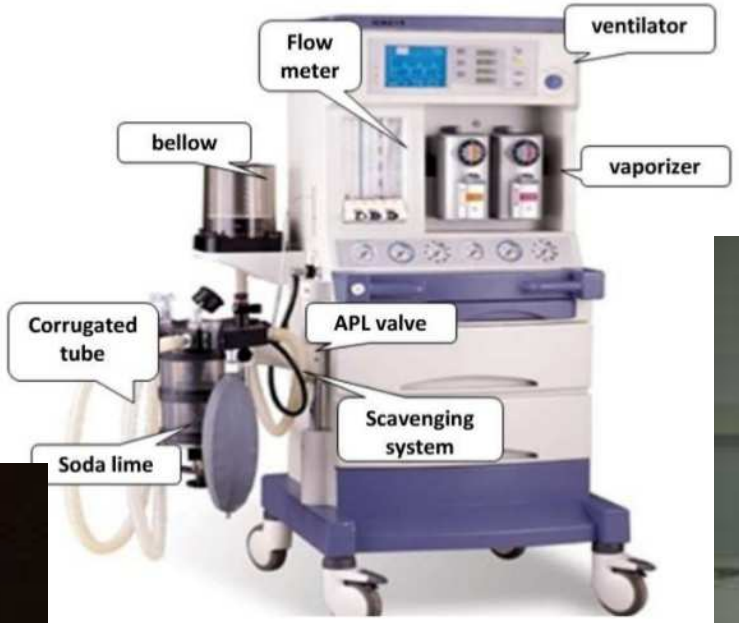
CLASS – B

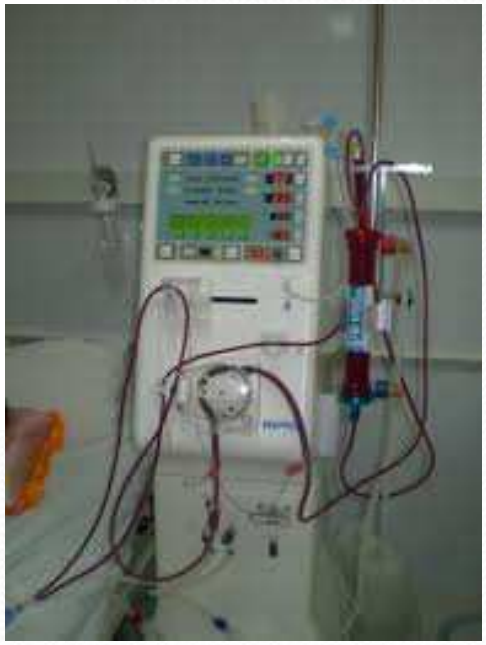
Controls for Class B devices

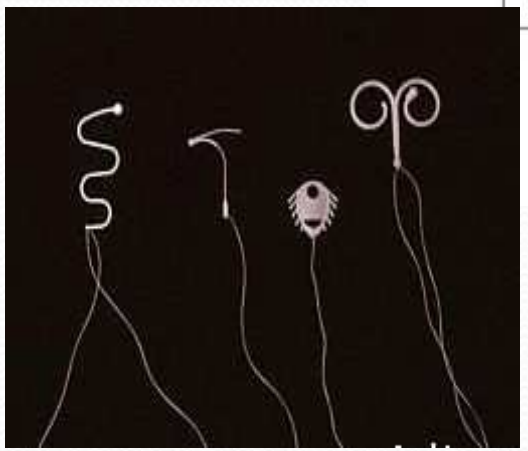
- Online application to CDSCO for registration of site and product
- Automatic transmission to a randomly selected Notified Body in case of domestic manufacturer and in case of imports CDSCO to take a call about in-house or external assessment.
- Class B devices to comply with:
- QMS
- Data requirements at the time of electronic submission of application
- Performance standards for functional conformance
- Biocompatibility
- Animal study (if any)
- Device Master File including essential requirements
- Labelling requirements
- Post Marketing Surveillance
- **No Clinical Trial/investigation data required**

Moderate High Risk

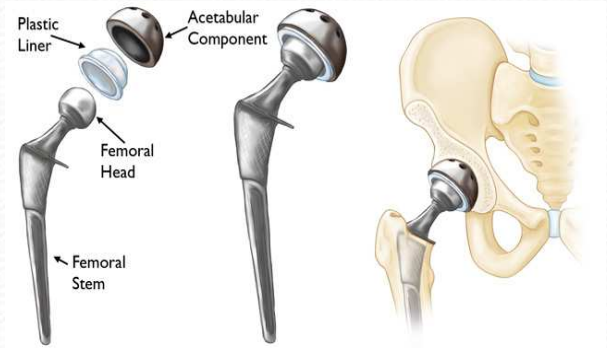
C L A S S I C





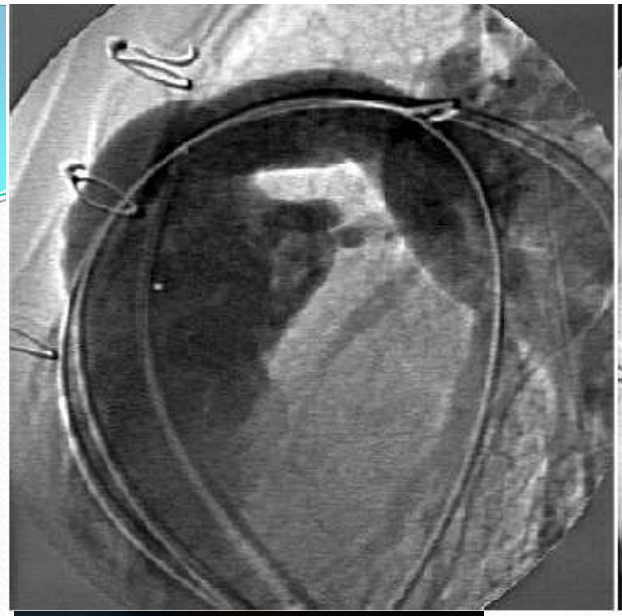


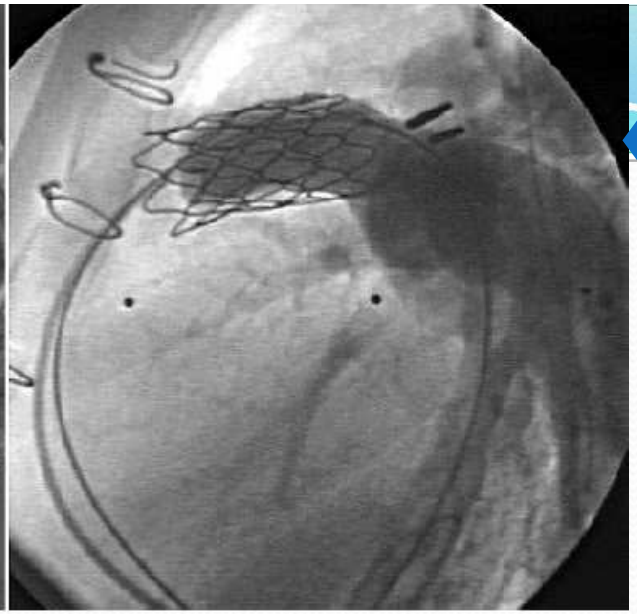
External Cardiac Pacemaker Dual Chamber (DDD)

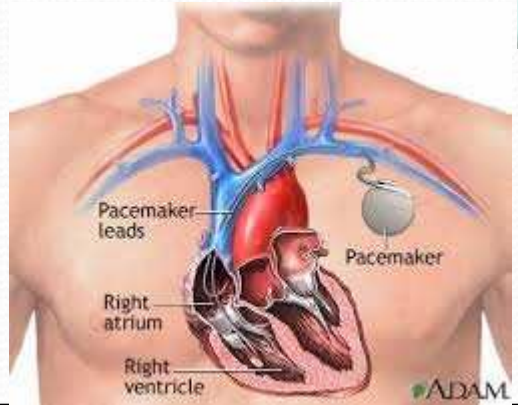


High Risk

CLASS I D







Controls for Class C & D devices

- Online application to CDSCO for registration of site and product
- Class C & D devices to comply with:
- QMS
- Functional conformance
- Biocompatibility
- Animal study (if any)
- Device Master File including essential requirements
- Labelling requirements
- Clinical investigation data
- Post Marketing Surveillance
- Sample of the device
- Device having predicate device exempted from clinical investigation data.

Requirements for approval of product

Regulatory Compliance	Class A	Class B	Class C	Class D
QMS	✓	✓	✓	✓
Electrical Safety/EMI/EMC testing data	*✓	*✓	*✓	*✓
Risk Analysis Report	✓	✓	✓	✓
Device Master File		✓	✓	✓
Biocompatibility data		**✓	**✓	**✓
Animal Testing			**✓	**✓
Clinical Data			***✓	***✓

* Only for Electrical supply based devices
**Only for invasive or implantable devices
***Only for Investigational devices

Regulatory Authorities

Scope of Regulation		Reviewer / Auditors	Regulatory Body
Clinical Investigation and approval of investigational medical devices		Medical Device Officer (MDO)/ Drugs Inspector (DIs)/ External subject experts	CDSCO
Import	All Class	MDO/ DI	CDSCO issue licence/ certificate
Manufacture	Class A&B	Notified Body	CDSCO
	Class C&D	MDO/ DI	
Sales		MDO/ DI (State officers)	State Licensing Authority

Notification of additional devices

- Devices to be notified along with its respective risk class by Central Government
- A committee of experts to be constituted to lay down criteria for classification and identification of devices to be notified
- International classification to be taken as the broad basis for classification
- CDSCO to place recommendations before DTAB with experts in relevant fields
- Phased notification of devices based on preparedness of regulatory structures
- Transition time to be provided

Removal of provisions for renewal of RC, Import, sale and manufacturing licence

- A registration certificate or import license shall remain valid, till it is suspended or cancelled from its date of issue
- Provided the applicant pays a certificate/licence retention fee on annual basis in the month of December.
- Provision for payment with late fee up to a maximum period of two months. After 2 months license will be deemed to have been cancelled.
- Manufacturer shall be audited on annual basis.
- Submission to CLA on changes in respect of site or significant changes in product, reportable complaints, recall etc.

Standards for medical devices

- QMS/ISO 13485
- Standards to be adopted for demonstrating compliance in respect of:

  1. Raw Material 2. Process 3. Product 4. Labelling

- Manufacturer to comply with:
- BIS standards, if available, or
- ISO/IEC standards, or
- Manufacturer's validated methods

Essential Principles of Safety and Performance

- General Requirements (Risk assessment, qualification of personnel etc.)
- Design and Manufacturing Requirements (material selection, verification and validation etc.)
- Requirements for medical devices connected to or equipped with an energy source
- Requirements for devices with a diagnostic or measuring function
- Protection against radiation
- Protection against mechanical risks
- Protection against risks posed to the patient by devices for self-testing or self-administration
- Clinical Evaluation

Human Resources

- A separate vertical with dedicated staff for medical devices
- Medical Device officers (MDO) in place of Drugs Inspectors
- Qualification of MDO
  - Biomedical Engineers
  - Electrical & Electronic Engineers
  - Plastics Engineers
  - Mechanical Engineers
  - Pharmacy
- External Subject Experts
- Contractual technical staff
- Training
- Accredited Notified Bodies (Class A & Class B)
- State Drugs Regulators (for sales)

Scope of Notified Bodies

- Only Class A and Class B medical Devices
- To verify QMS conformance at manufacturing site where necessary by inspection
- Verification of Essential Requirements
- Verifying validation of manufacturing process through objective evidence
- conformity of material with defined specifications
- Responsibility for ensuring conformance to QMS and conditions of license/registration
- CDSCO to audit notified bodies and test audit 5% of the licenses/registrations issued on the recommendation of each Notified Body

Registration & Regulation of Notified Bodies

- Only NABCB accredited Notified bodies to be registered with CDSCO
- Weightage to be given to accreditation by International bodies, but accreditation by NABCB will be mandatory
- ISO standards to be laid down in schedules to apply for accreditation/recognition
- System of Audit/inspection/unannounced Audits of Notified Bodies by CDSCO
- Schedule of fee to be charged by notified bodies to be prepared with provision for automatic upward revision based on WPI
- Refundable security deposit and revenue sharing model
- Duties, functions and obligations of notified bodies including penal provisions to be specified

IT Enabled Services

- Online submission, review and approval of applications
- E-learning programme
- Separate Online interface for Notified Bodies under CDSCO portal.
- Access to applicant, CDSCO and Notified Body through a single web based user interface
- Development of a centralized live database of registered establishments and devices
- Provisions of e-archival web based system for internal and public data

Capacity Building

- Manpower
  - Medical Device Officers
  - Technical Experts
- New Medical Devices Testing Centres
- Use of IT enable services
- Materiovigillance program
- New regulations
- Standard setting organisations
- Registration of Notified bodies


Thank you