Existing Related Standards

Exoskeleton Standard Technical Interchange Meeting; January 26-27, 2017; NIST, Gaithersburg

Burkhard Zimmermann; Technical project leader of JWG 36; IEC TC 62D & ISO TC 299 WG5

Hocoma

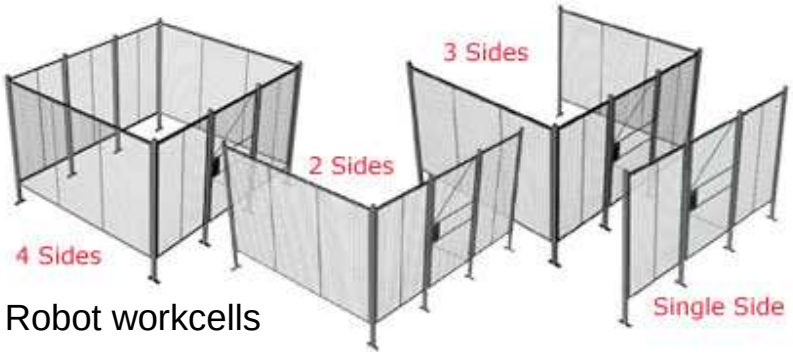
We move you

Summary of Presentation

- Changing world of robotics
  - Industrial ⇨ Service
- New requirements for personal care robots
  - ISO 13482:2014
- Wearable medical devices ; standards and other regulative aspects
- Conclusions

Traditional Industrial Robot Applications

- Powerful machines operating at high speeds and with great precision and dexterity
- Designed to operate in workcells separated from humans for safety

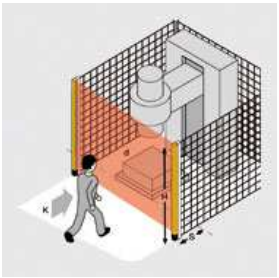


Robot workcells


Traditional robot workcell setup

Human access to the robot's operational space in the workcell is strictly controlled and regulated


Safety switches

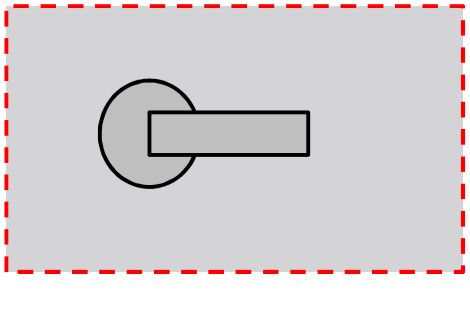




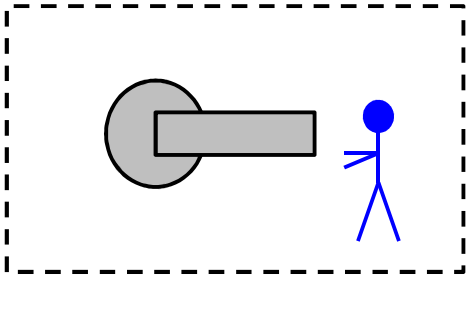
Light curtains, lasers and pressure mats, etc.

WG3: Industrial Robot Safety

Conventional industrial robots



Collaborative industrial robots



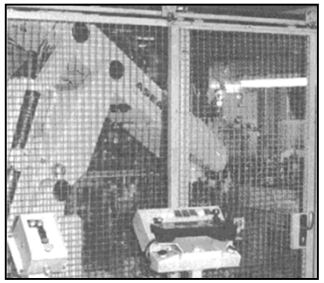
Safety zones

Discrete safety → No HRC

Safety controllers → Limited HRC

Harmless manipulators → Full HRC

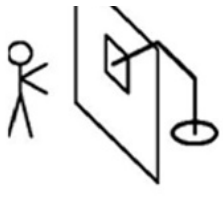
HRC: Human-Robot Cooperation



Absolute separation → Mixed environment

ISO 10218-1, -2; 2011
ISO TS 15066:
Collaborative robots

Handover window



Changing Scene of Robotics: Industry to Services

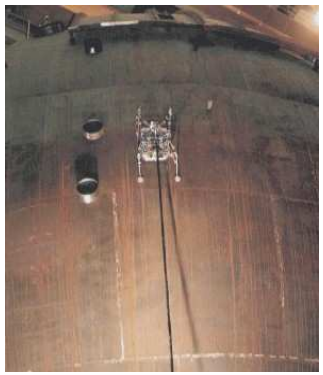
Manufacturing

Domestic

Military

INDUSTRIAL - SERVICES

Collaborative



Nuclear

Security

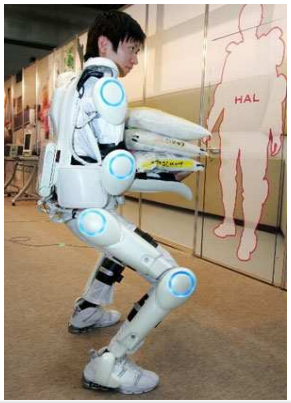
Mobile servant

Person carrier

Radiosurgery

Surgery

Rehabilitation

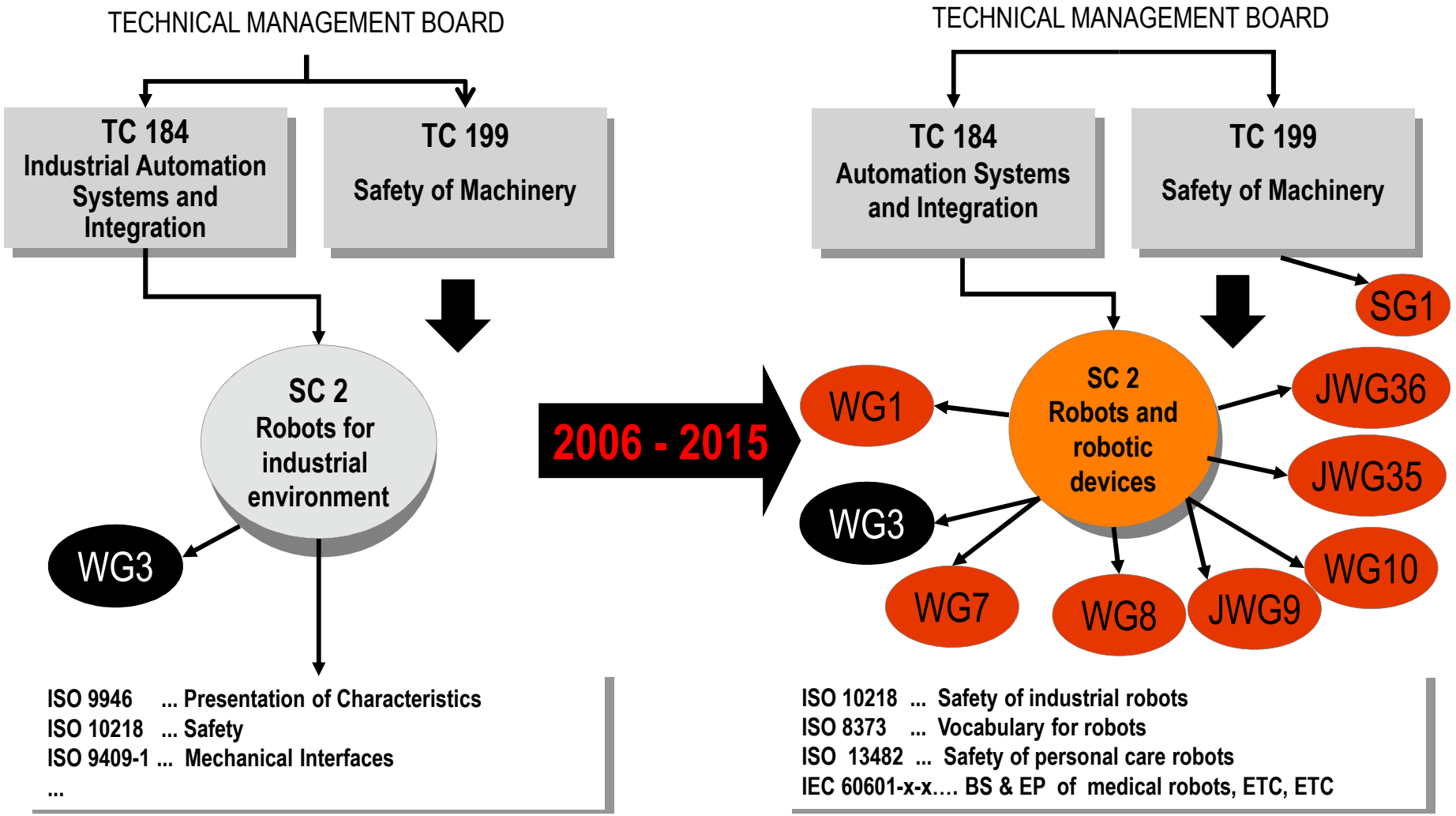


Physical assistant

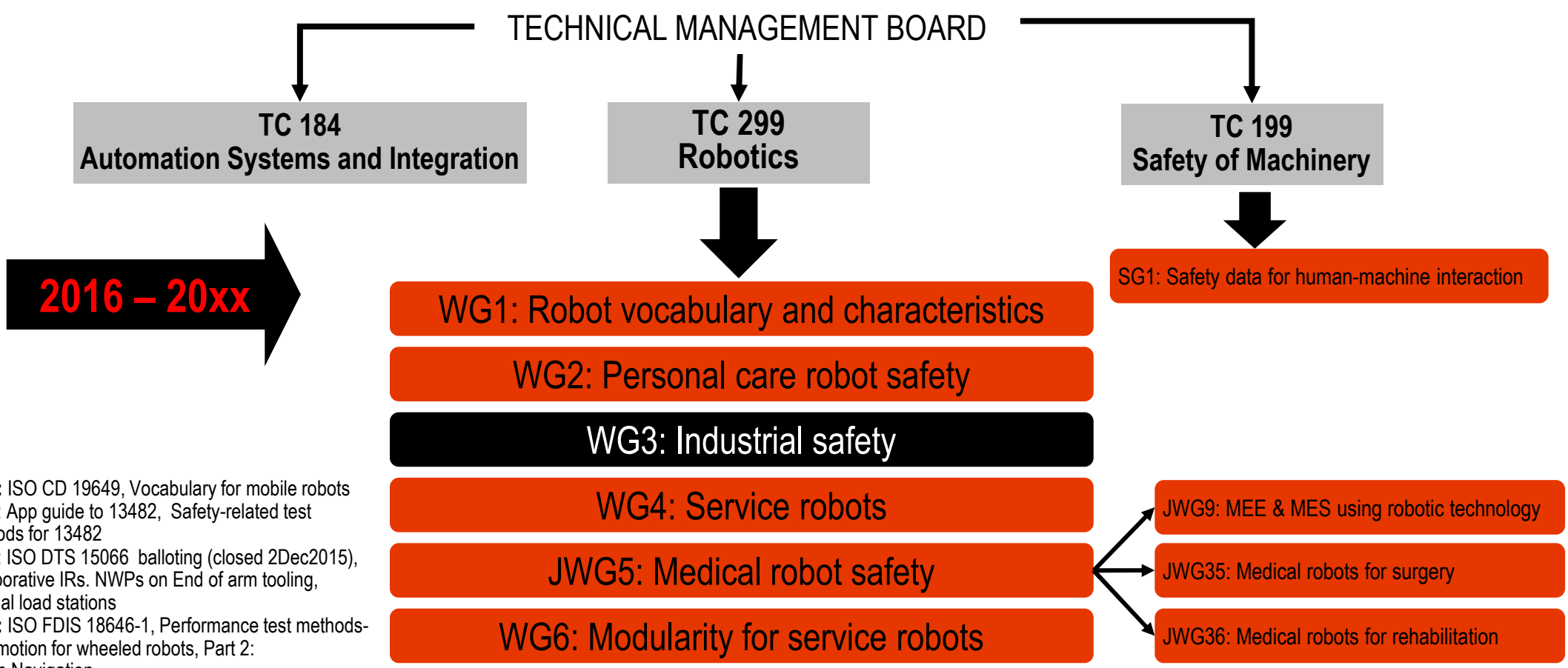
Distinction Between Industrial and Service Robots

	Industrial Robots	Service Robots
Working environments	Controlled and defined environments	Information structured/ unstructured environments
Users	Training for specified tasks in defined environments	Training to cover wide range of tasks in info structured/ unstructured environments
Safety	Machine dependent (ISO 10218-1)	Dependent on the robot and the user (ISO 13482)
Working philosophy	To keep robots and humans separated (see ISO 10218-1, -2; ISO PD TS 15066)	Robots and humans must share workspace for providing/ receiving the services (see ISO 13482)
Machine design	Flexible on commissioning for defined task	Flexible on demand for generic tasks/ users

Changing Face for ISO Robot Standardization



From Jan 2016: ISO TC 299 Robotics



- **WG1:** ISO CD 19649, Vocabulary for mobile robots
- **WG2**: App guide to 13482, Safety-related test methods for 13482
- **WG3**: ISO DTS 15066 balloting (closed 2Dec2015), collaborative IRs. NWPs on End of arm tooling, manual load stations
- **WG4:** ISO FDIS 18646-1, Performance test methods-Locomotion for wheeled robots, Part 2: CD on Navigation
- **WG5**: IEC TR CD 60601-4-1, MEE with DOA; IEC 80601-2-77, BS&EP Med robots for surgery; IEC 80601-2-78, BS&EP Med robots for rehab
- **WG6:** Modularity for service robots – Part 1: General requirements

ISO 10218-1:2011, Safety requirements for industrial robots:
ISO 8373:2012, Vocabulary for robots

ISO 10218-2:2011, Robot systems and integration
ISO 13482:2014, Safety requirements for personal care robots

Slide provided by Prof. Gurvinder Virk

Generic Safety Design Methodology

- ISO 12100 defines a standard approach to designing machines to achieve safety requirements:
  1. First, try to achieve the safety requirements by means of inherently safe design
  2. If inherently safe designs are not possible, then try to achieve the requirements by means of safeguarding or protective measures
  3. If neither of these solutions are possible, then provide information for use to the operator (warnings, instructions) to assist the operator in achieving acceptable safety
  4. (implicit) If none of these are possible, then acceptable safety cannot be achieved and the machine should not be used
- Harmonised safety standards for robots
  - EN ISO 10218-**1**:2011, Safety requirements for industrial robots – Robots
  - EN ISO 10218-**2**:2011, Safety requirements for industrial robots – Robot systems and integration
  - **EN ISO 13482: 2014, Safety requirements for personal care robots**

ISO Definition: Robot

- Old ISO 8373 definition: industrial robot
  - an automatically controlled, reprogrammable, multipurpose manipulator, programmable in three or more axes which may be either fixed in place or mobile for use in industrial automation applications
- Current ISO 8373 (2012) definition: robot
  - actuated mechanism programmable in two or more axes with a degree of autonomy, moving within its environment, to perform intended tasks
- New ISO TC299 definition: robot
  - programmed actuated mechanism with a degree of autonomy, moving within its environment, to perform intended tasks

WG1: Latest Robot Definitions

- **Service Robot:** robot that performs useful tasks for humans or equipment excluding industrial automation applications
- **Industrial Robot:** automatically controlled, reprogrammable multipurpose manipulator, programmable in three or more axes, which can be either fixed in place or mobile for use in industrial automation applications
- **Autonomy:** ability to perform the intended tasks based on current state and sensing, without human intervention; *medical robots use anther definition*
- **Personal Care Robot:** service robot that performs actions contributing directly towards improvement in the quality of life of humans, excluding medical applications
- **Medical Robot:** a robot intended to be used as medical electrical equipment (MEE) or as medical electrical systems (MES)

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  - ISO 13482:2014
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New Requirements for Personal Care Robots

WG2: Personal care robot safety (non-medical). ISO 13482:2014

1. **Mobile servant robot:** personal care robot that is capable of travelling to perform serving tasks in interaction with humans, such as handling objects or exchanging information
2. **Physical assistant robot (PAR):** personal care robot that physically assists a user to perform required tasks by providing supplementation or augmentation of personal capabilities
   - restraint type PAR: PAR that is fastened to a human during use
   - restraint-free type PAR: PAR that is not fastened to a human during use
3. **Person carrier robot:** personal care robot with the purpose of transporting humans to an intended destination.

1. Mobile servant

2. Physical assistant

3. Person carrier robot

Specific Safety Clauses in 13482

Safety requirements and protective measures.
Hazards due to:

- Charging battery
- Energy storage and supply
- **Robot shape**
- **Emissions**
- Electromagnetic interference
- **Stress, posture and usage**
- **Robot motion**
- Insufficient durability
- **Incorrect autonomous actions**
- **Contact with moving components**
- Lack of awareness
- Environmental conditions
- Localization & navigation errors

Safety related control system requirements for:

- Robot stopping
- Safety related speed control
- Safety related environmental sensing
- **Stability control**
- Safety related force control
- **Singularity protection**
- **Design of human interface**
- **Manual control devices**
- **Operational modes**

EN ISO 13482: Safety requirements for personal care robots published in Feb 2014

Current Work Within ISO TC 299; WG2; Personal care robot safety;

- **ISO 13482:2014**

  Robots and robotic devices -- Safety requirements for personal care robots (published)

- **ISO/CD TR 23482-1**

  Robotics -- Application of ISO 13482 -- Part 1: **Safety-related test methods** (*underway*)

- **ISO/CD TR 23482-2**

  Robotics -- Application of ISO 13482 -- Part 2: **Application guide** (*underway*)

Current Contents of ISO 13482

"Vertical" combination = Characteristic of robot

"Horizontal axis": diversity of technology

Basic technologies

Mechanics | Electronics | Pneumatics | Hydraulics | Software | Security

Intelligence functions

Navigation | Collision avoidance | Human interface | Balance control | Force control

Common technologies

Personal care robot is a service robot that performs actions contributing directly towards improvement in the quality of life of humans, excluding medical applications

Type specific personal care robots

Mobile servant

Personal care robot that is capable of travelling to perform serving tasks in interaction with humans, such as handling objects or exchanging information

Person carrier

Personal care robot with the purpose of transporting humans to an intended destination

Physical assistant

Personal care robot that physically assists a user to perform required tasks by providing supplementation or augmentation of personal capabilities

- Restraint type: physical assistant robot that is fastened to a human during use
- Restraint-free type: physical assistant robot that is not fastened to a human during use

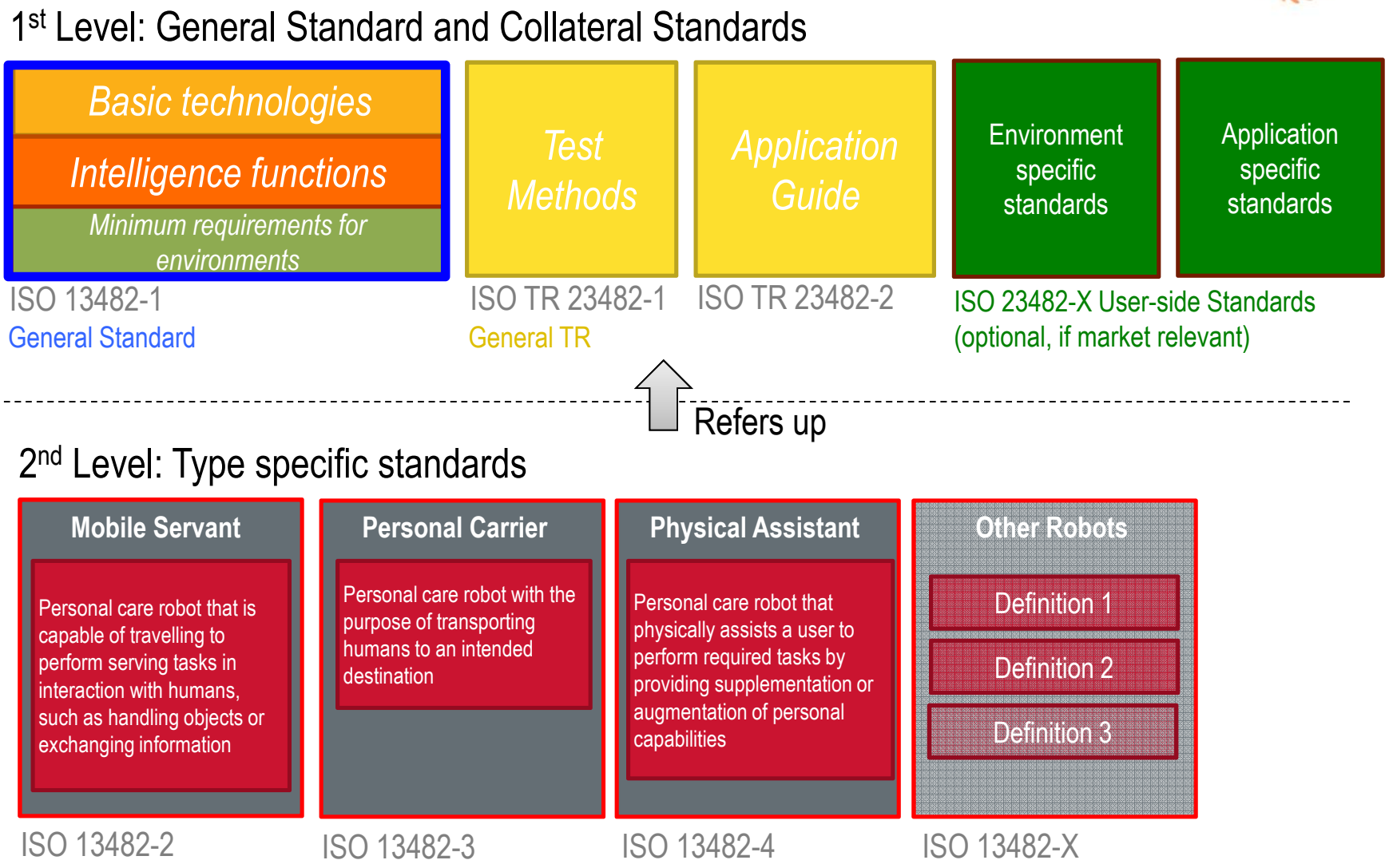
Type specific technologies

Environments

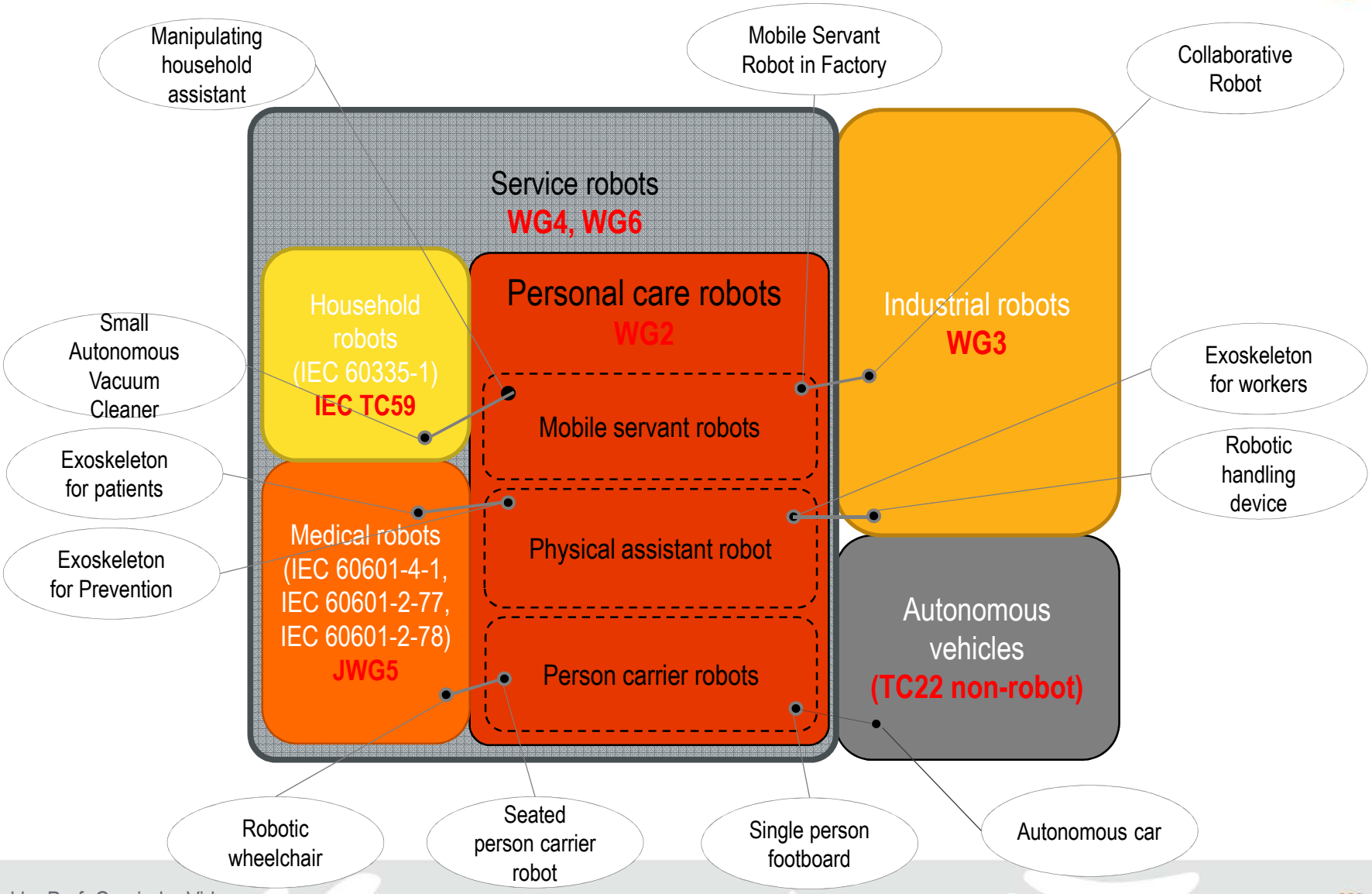
Minimum requirements for environments (EMC, Protection from ingress/dust…)

Slide provided by Prof. Gurvinder Virk

Possible Restructuring of ISO 13482



Inter-TC299: WG2 Interaction to Other WGs



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Wearable medical device development; exoskeletons
Standards and other regulative aspects

1. What is a medical device (MD)?

2. What are main regulative aspects for a MD?

3. Which standards should be observed for MD
   in the area of exoskeletons

1.) What is a Medical Device?

Definition for MEDICAL DEVICE:

- There is no worldwide uniform definition
- Definitions given in MD registration requirements and standards are different

When is a device a MEDICAL DEVICE

- Defined from the manufacturer of the MD by the intended use!

2.) Main Regulative Aspects During Development

Good manufacturing practice system in place

- Most countries accepted / requires quality managements systems (based on / or according to) ISO 13485 (with national deviations or additional); US: 21 CFR Part 820

Complete technical file for each kind of MD

Medical device registrations through national authorities

- Most countries differentiate between MD- categories based on different “risk-” levels
  - according to defined rules, or according to lists of generic types of MD`s
- Evidence of fulfilment of MD regulations is mostly needed
  - range depends on risk-class and national requirements
  - very often international standards are used to demonstrate MD conformity about specific aspects
  - → performance must be shown by clinical data!! (not based on international standards (norms))

2.) Main Regulative Aspects During Development

Complete technical file for each kind of MD

US (21 CFR Part 820)

- Sec. 820.3 Definitions
  (e) *Design* history *file* (*DHF*) means a compilation of records which describes the design history of a finished device.
- 820.30 Design control
  (j) *Design history file.* Each manufacturer shall establish and maintain a DHF for each type of device. The DHF shall contain or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of this part.

International

- Summary Technical Documentation (STED) for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices
  http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n063-2011-summary-technical-documentation-ivd-safety-conformity-110317.pdf

2.) Main Regulative Aspects During Development

Medical device registrations through national authorities

- In most countries the efficiency of the medical device must be shown based on clinical data
- Most interesting aspects for e.g. therapeutic devices:
  - ➔ patient outcome (improvement)
  - ➔ That`s much more interesting than the fulfilment of technical parameters provided by performance standards

Conclusion:

➔ **No need for performance standards in the area of medical exoskeletons**

Examples for MD Regulations *) (EU)

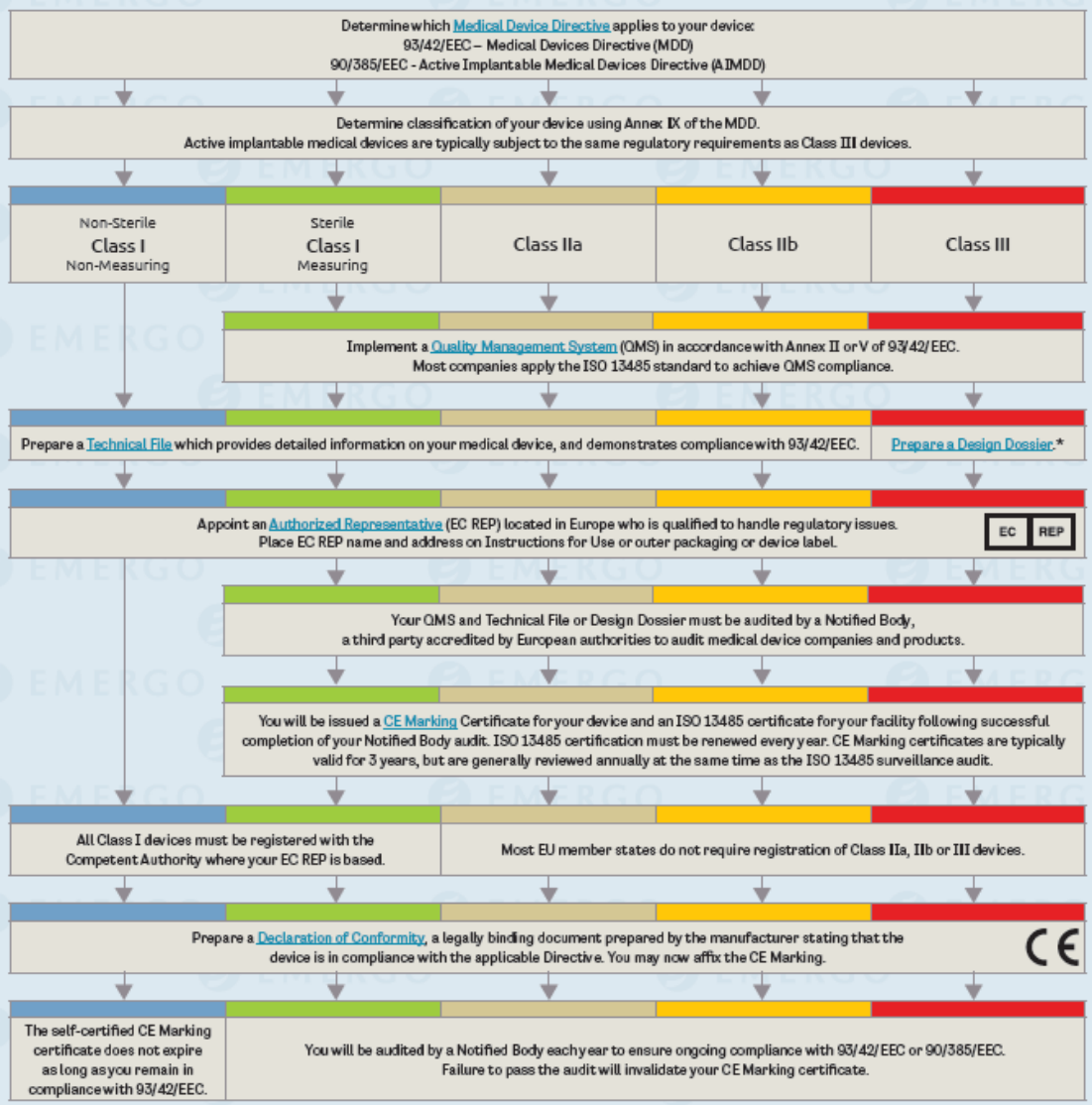
Medical Device Regulation … on the way (MDD at the moment 68 pages ➔MDR will be 680 pages… or more)

Device classification in Europe	How long you should expect to wait after submission until approval is granted. (See note 1)	Validity period for CE Marking certificate. (See note 2)	Registration renewal should be started this far in advance. (See note 3)	Complexity of the registration process for this classification. (See note 4)	Overall cost of gaining regulatory approval. (See note 5)
CLASS I * Non-sterile, non-measuring	<1 month	Does not expire	Not applicable	Simple – Complex	Low – High
CLASS I Sterile, measuring	3-5 months	3 years	2 months	Simple – Complex	Low – High
CLASS IIa	3-5 months	3 years	2 months	Simple – Complex	Low – High
CLASS IIb	3-6 months	3 years	2 months	Simple – Complex	Low – High
CLASS III	6-9 months	3 years	2 months	Simple – Complex	Low – High

* Class I devices which are not provided sterile and which do not have a measuring function can be self-certified (self-declared).

*) all graphics are publicly accessible: http://www.emergogroup.com

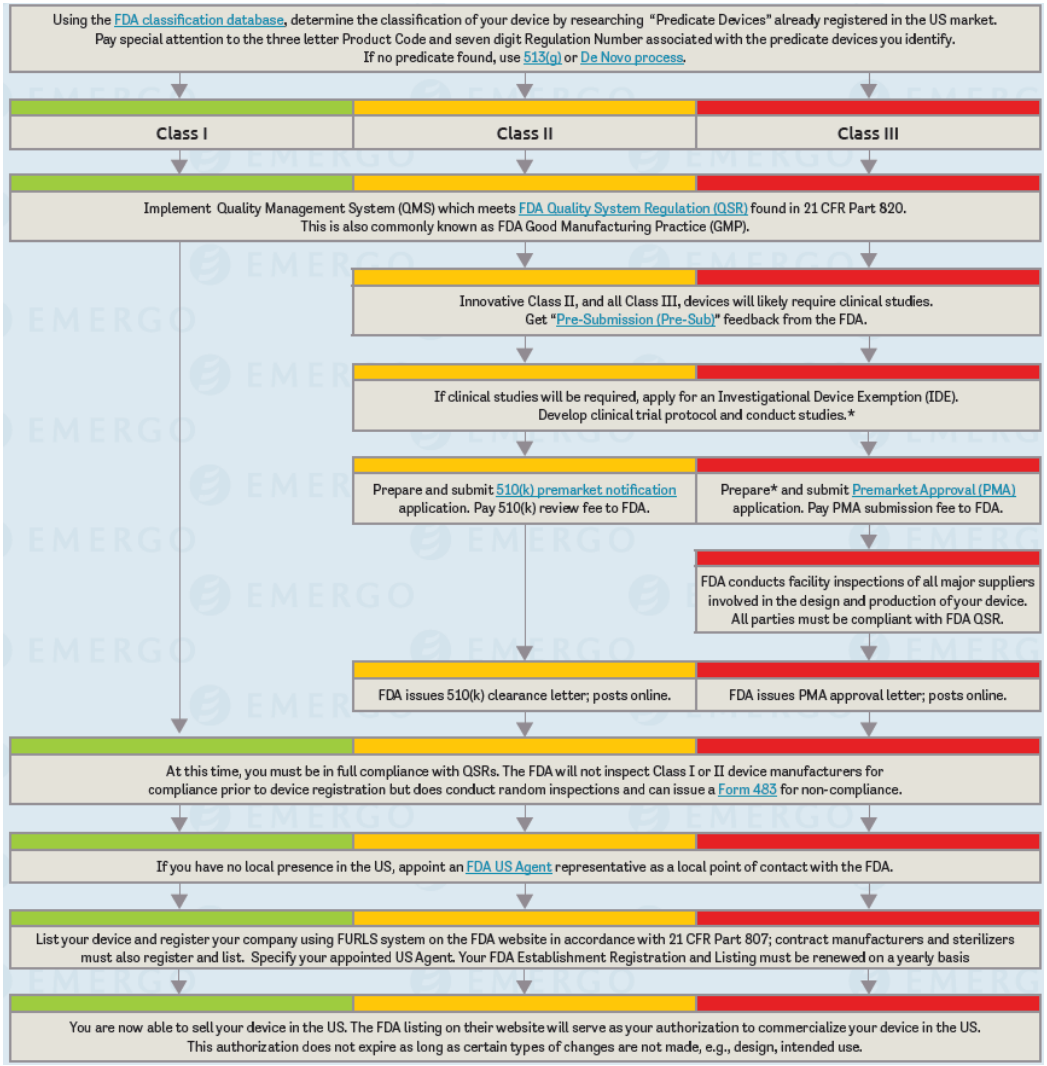
Examples for MD Regulations EU



Examples for MD Regulations (USA)

Device classification in USA	How long you should expect to wait after submission until approval is granted. (See note 1)	Validity period for device registrations. (See note 2)	Registration renewal should be started this far in advance. (See note 3)	Complexity of the registration process for this classification. (See note 4)	Overall cost of gaining regulatory approval. (See note 5)
CLASS I*	1 month	Does not expire	Not applicable	Simple — Complex	Low — High
CLASS II	3-6 months	Does not expire	Not applicable	Simple — Complex	Low — High
CLASS III**	18-30 months	Does not expire	Not applicable	Simple — Complex	Low — High

Examples for MD Regulations (USA)



MD Registrations

Summary MD registration:

- Medical device registrations in different countries are following the same general approach but the way to get the required national approvals variates in the details.
  - Post market surveillance is also required
    - Including incident or trend reporting
    - Maintain your technical file; including risk management and usability processes and clinical evaluation
    - Customer feedback system
    - …
  - Design changes are related to existing MD registrations
  - Re-registration and re-certification activities
  - Payment of yearly fees for MD registrations
  - Audits from national authorities (announced and unannounced)
  - Factory inspections from third parties
  - Regularly reporting to national authorities or third parties
  - Technical maintenances including required safety inspections of your MD

3.) Which Standards should be observe for MD

… a lot … a view… depends on your medical device

The most important standardization organizations in the area of medical devices are:

International **E**lectrotechnical **C**ommission

International **O**rganization for **S**tandardization

… for “medical” exoskeletons the **IEC 60601- series** is main important

3.) Which Standards Have to Observe for MD

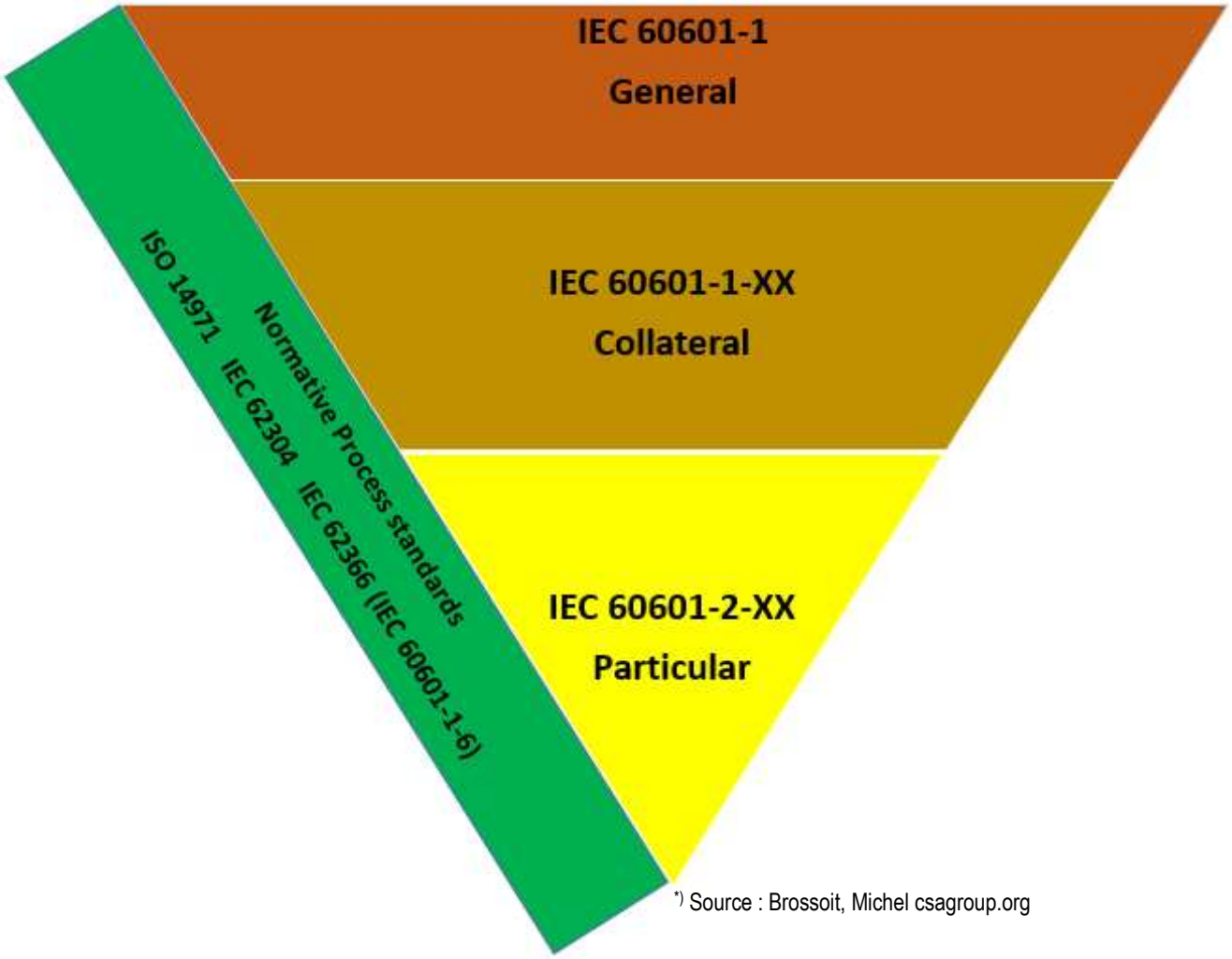
- **IEC TC 62 Electrical equipment in medical practice; 62 Scope**

To prepare international standards and other publications concerning electrical equipment, electrical systems and software used in healthcare and their effects on patients, operators, other persons and the environment.

- NOTE : This scope includes items that are also within the scopes of other committees and will be addressed through cooperation. Attention will focus on safety and performance (e.g. radiation protection, data security, data integrity, data privacy and environmental aspects) and will contribute to regulatory frameworks. **Healthcare includes medical practice as well as emergency medical services, homecare, and support of persons with disabilities in their daily lives (i.e. Ambient Assisted Living).**

IEC 60601(3rd) - Family

2nd amendment underway; 4th edition already planed



*) Source : Brossoit, Michel csagroup.org

TC 62A Publications (~12)
standards & technical reports and amendments
(different versions / year of publication)

TC 62A Publications (~45)
standards & technical reports and amendments
(different versions / year of publication)

TC 62D Publications (~80)
standards & technical reports and amendments
(different versions / year of publication)

IEC 60601 Standard Series

“Basic standard” IEC 60601-1

Edition 3.1 2012-08 **Medical electrical equipment – Part 1: General requirements for basic safety and essential performance**

1 Scope, object and related standards

1.1 * Scope

1.2 Object

1.3 * Collateral standards

1.4 * Particular standards

2 * Normative references

3 * Terminology and definitions

4 General requirements

5 * General requirements for testing ME EQUIPMENT

6 * Classification of ME EQUIPMENT and ME SYSTEMS

7 ME EQUIPMENT identification, marking and documents

8 * Protection against electrical HAZARDS from ME EQUIPMENT

9 * Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

10 * Protection against unwanted and excessive radiation HAZARDS

11 * Protection against excessive temperatures and other HAZARDS

12 * Accuracy of controls and instruments and protection against hazardous outputs

13 * HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

14 * PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

15 Construction of ME EQUIPMENT

16 * ME SYSTEMS

17 * Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

IEC 60601 Standard Series

1.1 * Scope

This International Standard applies to the **BASIC SAFETY** and **ESSENTIAL PERFORMANCE** of **MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS,** hereafter referred to as ME EQUIPMENT and ME SYSTEMS.

3.63 * MEDICAL ELECTRICAL EQUIPMENT (ME EQUIPMENT)

electrical equipment having an APPLIED PART or transferring energy to or from the PATIENT or detecting such energy transfer to or from the PATIENT and which is:

a) provided with not more than one connection to a particular SUPPLY MAINS; and

b) intended by its MANUFACTURER to be used:

1) in the diagnosis, treatment, or monitoring of a PATIENT; or

2) for compensation or alleviation of disease, injury or disability

IEC 60601 Collateral Standards; which should considered for exoskeletons

- **Medical electrical equipment—Parts 1–2 General requirements for basic safety and essential performance—Collateral Standard: Electromagnetic compatibility—Requirements and tests (IEC 60601–1-2:2007)**
- **Medical electrical equipment—Parts 1–6: General requirements for basic safety and essential performance—Collateral Standard: Usability (IEC 60601–1-6:2010)**
- Medical electrical equipment—Parts 1–8: General requirements for basic safety and essential performance—Collateral Standard: General requirements, tests, and guidance **for alarm systems** in medical electrical equipment and medical electrical systems (IEC 60601–1-8:2006)
- **Medical electrical equipment—Parts 1–9: General requirements for basic safety and essential performance—Collateral Standard: Requirements for environmentally conscious design (IEC 60601–1-9:2007)**
- Medical electrical equipment—Parts 1–10: General requirements for basic safety and essential performance—Collateral Standard: Requirements for the development of **physiologic closed-loop controllers** (IEC 60601–1-10:2007)
- **Medical electrical equipment—Parts 1–11: General requirements for basic safety and essential performance—Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment (IEC60601–1-11:2010)**

IEC 60601 Collateral Standards; which should considered for exoskeletons

1.4 * Particular standards

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in this standard as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

Potential applicable particular standards for wearable medical robots (exoskeletons):

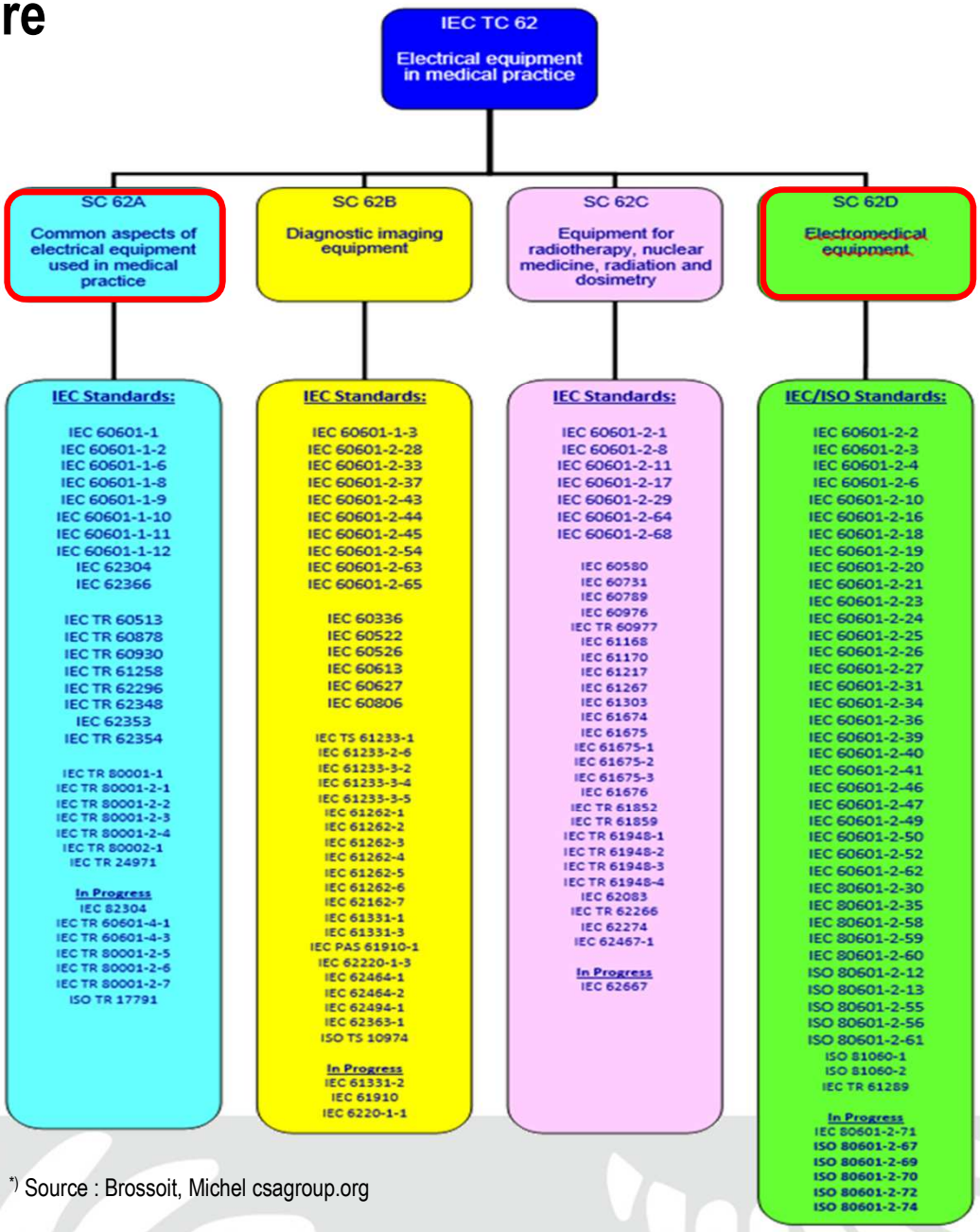
- Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators (published)
- IEC 80601-2-78 Particular requirements for the basic safety and essential performance of **MEDICAL ROBOT for rehabilitation, assessments, compensation or alleviation of disease, injury or disability**
  in preparation

IEC 60601-1 Test Report

- ~150 Test report templates for the IEC 60601 standard family
  https://webstore.iec.ch/searchform&q=IECEE%20TRF%2060601

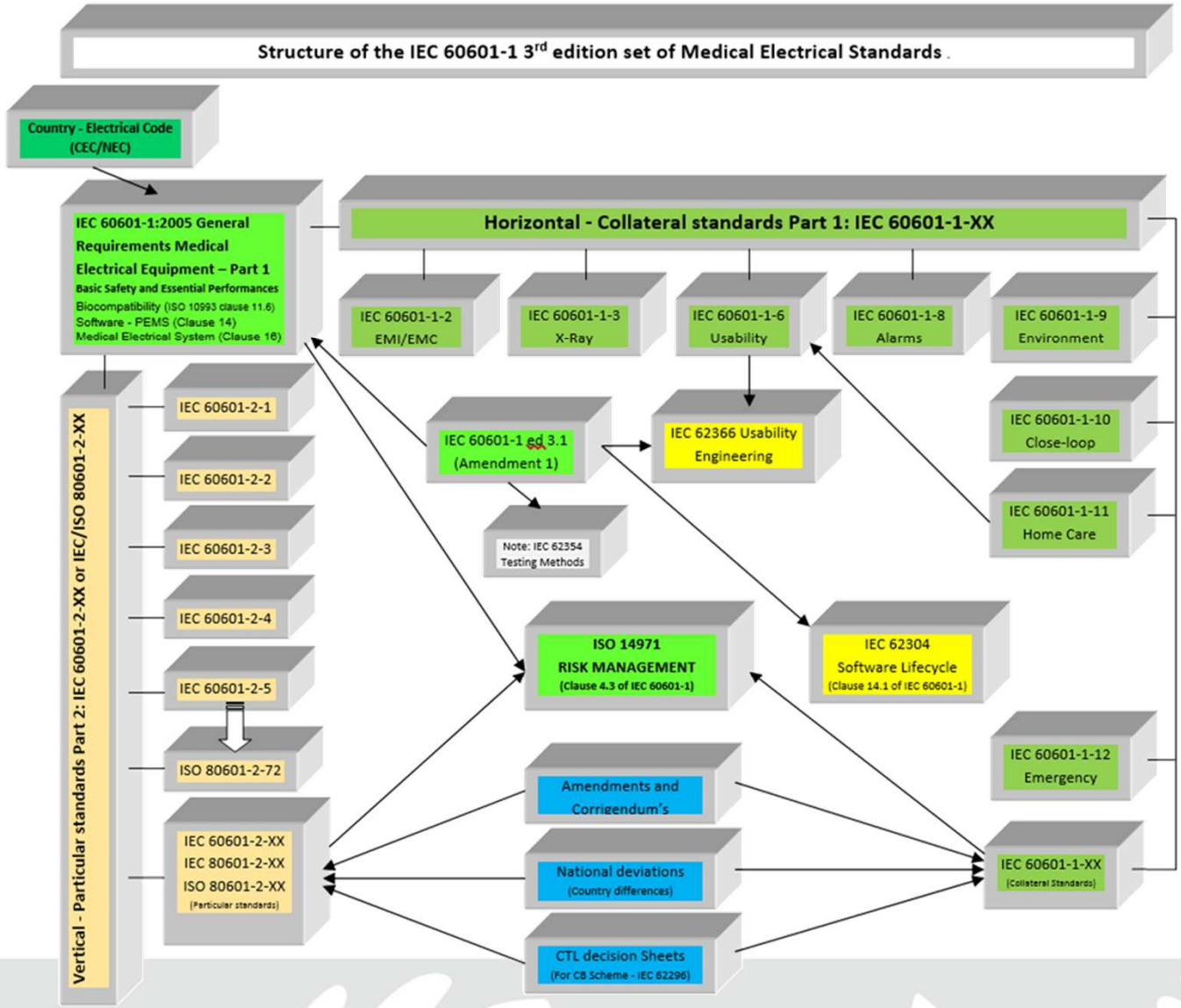
- Internally we use already a test dummy:

IEC 60601 Structure



*) Source : Brossoit, Michel csagroup.org

Interconnection of the IEC 60601 Series



*) Source : Brossoit, Michel csagroup.org

Other Important IEC & ISO Standards

- **Software**

  IEC 62304:2006; Medical device software - software life cycle processes

GUIDELINES ABOUT SOFTWARE AND SOFTWARE DEVELOPMENT CYCLE

- Design Control Guidance for Medical Device Manufacturers; FDA Center for Devices and Radiological Health. http://www.fda.gov/downloads/Medical/DeviceRegulationandGuidance/GuidanceDocuments/ucm085371.pdf
- General Principles of Software Validation, Final Guidance for Industry and FDA Staff; FDA Center for Devices and Radio logical Health. http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085371.pdf
- Title 21—Food and Drugs; Chapter I—Food and Drug Administration; Department of Health and Human Services; Subchapter A—General Part 11 Electronic Records; Electronic Signatures. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11&showFR=1
- Guidance for Industry Part 11, Electronic Records; Electronic Signatures—Scope and Application U.S. Department of Health and Human Services; Food and Drug Administration. http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm125125.pdf
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices; U.S. Department of Health and Human Services; Food and Drug Administration; Center for Devices and Radiological Health; Office of Device Evaluation. http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089593.pdf

Other Important IEC & ISO Standards

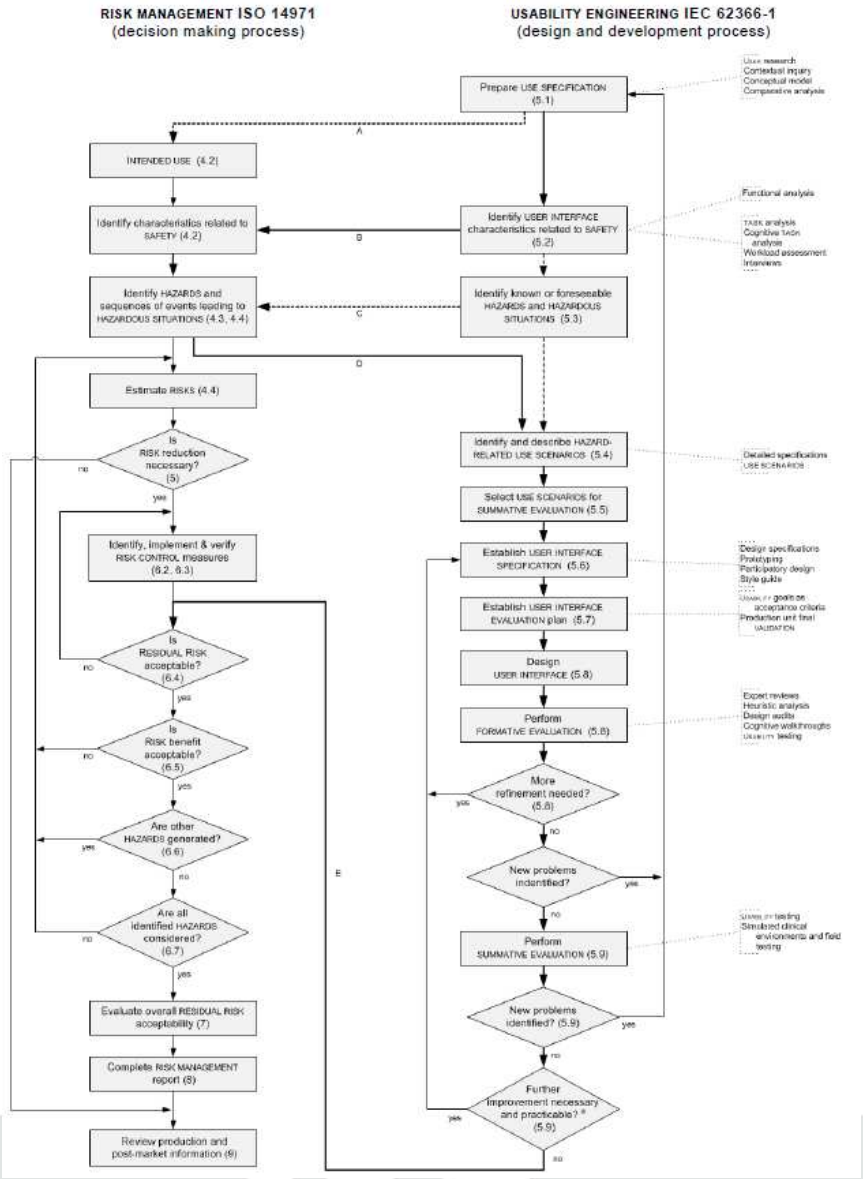
- **Usability**

  IEC 62366-1:2015
  Medical devices - Part 1: Application of usability engineering to medical devices
  IEC 60601-1-6:2010+AMD1:2013 CSV
  Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

- **Riskmanagement**

  ISO 14971:2007
  Medical devices -- Application of risk management to medical devices

Relationship between Risk Management and Usability Engineering



*) Source : IEC 62366-1:2015-02 Medical devices –
Part 1: Application of usability engineering to medical devices

Other Important IEC & ISO Standards

- **Product specific standards**
  ISO 10535:2006

  Hoists for the transfer of disabled persons -- Requirements and test methods
- **Biocompatibility**

  ISO 10993- series (24 documents)

  Biological evaluation of medical devices -- Part 1: Evaluation and testing within a **risk management process**
- **Maintenance**

  IEC 62353:2014
  Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment
- **Medical devices in IT-networks**

  IEC 80001-series (8 documents)
  Application of risk management for IT-networks incorporating medical devices - Part 1: Roles, responsibilities and activities
- **NWP for refurbishment of medical devices**

General Statement about medical robots including exoskeletons

After several months of working on RACA ROBOTS and SURGERY ROBOTS and additionally six years on MEDICAL ROBOTIC, the JWG 35 & 36 project group leaders believe that:

- There are only a view topics which really relate to robotic technology in IEC 80601-2-77 and IEC 80601-2-78
  - Operator situation awareness with a high degree of autonomy as part of the usability engineering
  - More focus on risk management is needed for MEE / MES which have a high degree of autonomy

  Both aspects are already covered by IEC 60601-1 and are adopted during each 80601-2-xx work according to the specific application of MEE/ MES.

- All other specific aspects which we identified during our work on IEC 80601-2-77 and IEC 80601-2-78 are more related to the specific application of the MEE / MES than to the DEGREE OF AUTONOMY or to the robotic technology

General Statement about medical robots

During the **Workshop on Medical robot standardization hold in** Orlando, Florida, USA at November 7th, 2016 the following national regulatory agencies

- U.S. Food and Drug Administration (FDA)
- Korean Food and Drug Administration (KFDA);
- Pharmaceuticals and Medical Devices Agency and the Ministry of Health, Labor and Welfare (PMDA);

confirmed that medical robots would be seen as «normal» medical devices, which could be handled according to existing regulations in their countries!

Summary:
Neither standards nor medical device regulations seen robotic technology as something specific, it always depends on the application / intended use

Summary Medical Device

1. What is a medical device?
   - Intended use given from the manufacturer defines, if a device is a medical device
   - Several definitions exist

2. What are main regulative aspects during the development of a MD?
   - Good manufacturing practice system must be in place; **including the design & design change process**
   - **Medical device product registrations** through national authorities **based on a product specific technical file including clinical data** are mostly needed
   - Evidence about **fulfilment of MD regulations** is required

   National MD registrations systems base on these aspects, but differentiate in details

3. Which standards should be observe for MD
   - IEC 60601 series and the referenced standards in IEC 60601
   - other medical and non medical standards can be helpful to show conformity

Summary Medical Device

- One of the main objective of the “Medical Standards” is the **Patient**
- The word **“PATIENT”** is unique for “Medical Standards”
- Other standards address **USER** safety
- Medical standards address **PATIENT** and **USER** safety
- Additionally, MD`s have to fulfil national / regional requirements
- **Medical devices including exoskeleton are already highly regulated**

Summary of Presentation

- Changing world of robotics
  - Industrial ⇨ Service
- New requirements for Personal Care Robots
  - ISO 13482:2014
- Wearable Medical Devices ; standards and other regulative aspects
- Conclusions

Conclusion

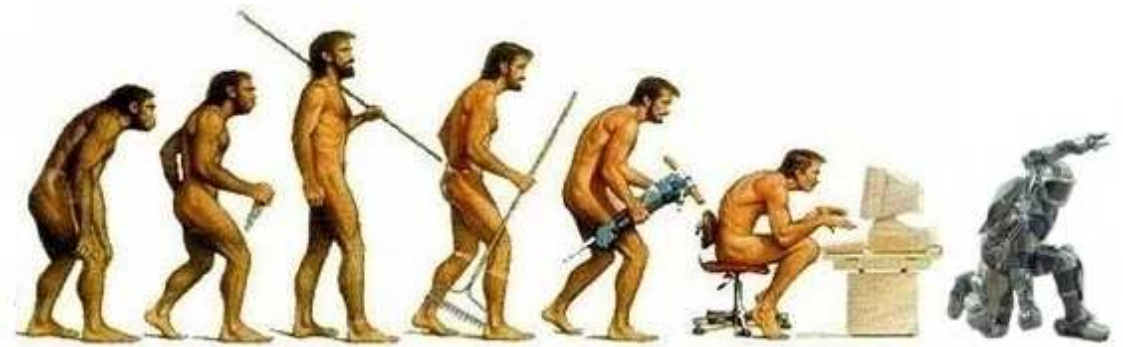
- **Different application areas for exoskeletons create different safety and maybe other boundary conditions**
  - Military
  - Industrial
  - Service
  - Personal care
    - Mobile servant robot
    - Physical assistant robot
    - Person carrier robot
  - Medical
  - …

- **Differentiate between different kinds of exoskeletons**
  - None walking Exoskeletons (upper extremities)
  - Free-walking Exoskeletons
  - Stationary Exoskeletons
  - ...
  - Upper and lower extremities
  - Intended to be used by: soldiers, workers, elderly, handicapped, patient (adult; pediatric), …

for future standardization work

Thank you very much for your attention!

Special thanks to Prof Gurvinder Virk; Convenor of several ISO TC 299 working and joint working groups, for providing a couple of slides



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