Standards & Regulations Presentation

ISO 10993 & ISO 13485

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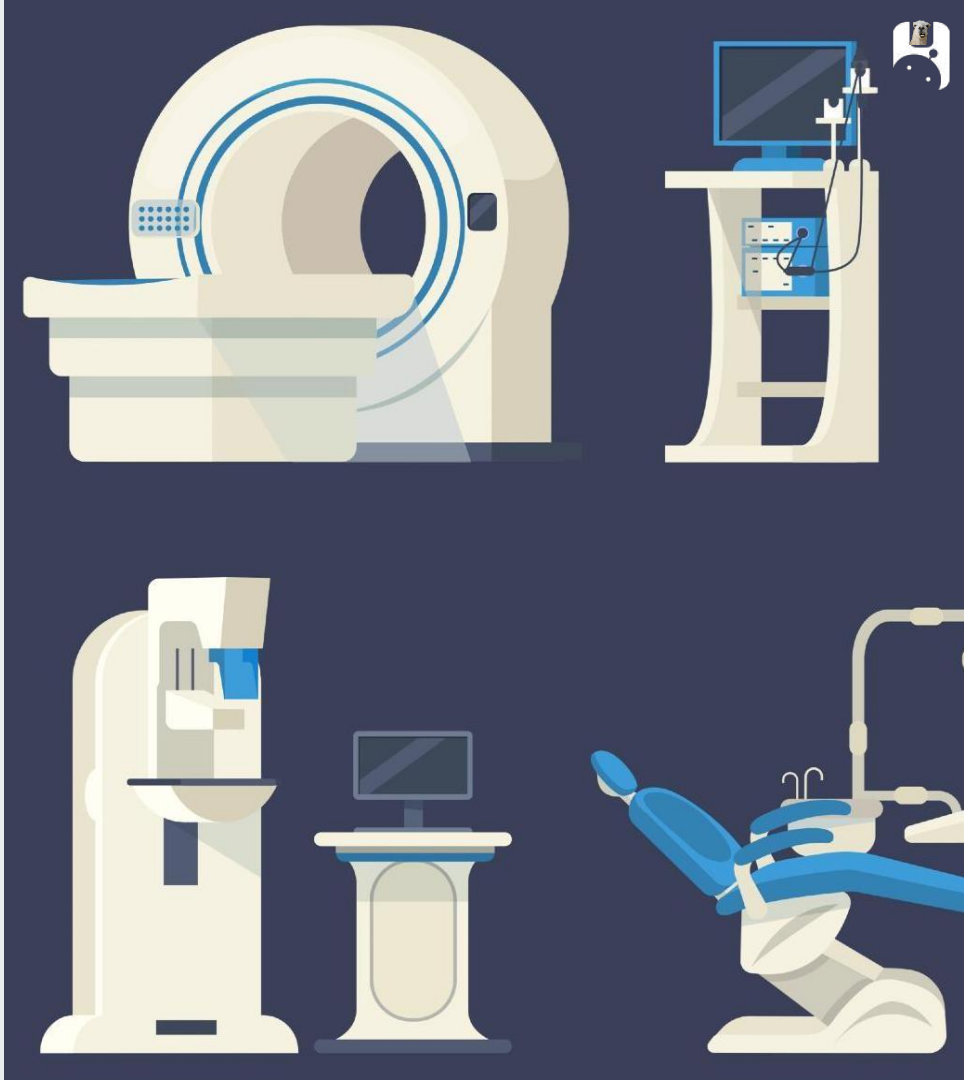
ISO 10993

Biological Evaluation of Medical Devices



What is it about?

Goal: Protect humans from potential ***biological risks*** arising from the use of medical devices

Provides a ***framework*** in which to plan a ***biological evaluation*** and evaluate the resulting risks

- Not a rigid test plan, experts must plan tests themselves

Evaluation should include consideration of:

- Medical device geometry
- Area of application
- Materials
- Physical and chemical characteristics
- History of clinical or human use
- Toxicology or biological safety data
- Test procedures

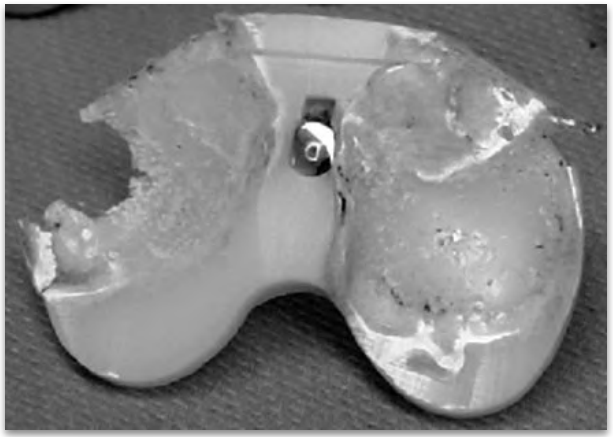
Why should we care? [Biocompatibility Issues]

Biocompatibility: ability of a medical device or material to perform with an ***appropriate host response*** in a specific application

Potential unwanted host responses could include ***blood clotting***, ***inflammation***, ***local tissue degradation***, etc.

Furthemore, if a device is not biostable, it could lead to ***premature degradation*** due to wear

Medical Devices: any ***instrument***, apparatus, implement, machine, appliance, ***implant***, or reagent intended by a manufactured to be used on human beings for medical purposes



Product Application

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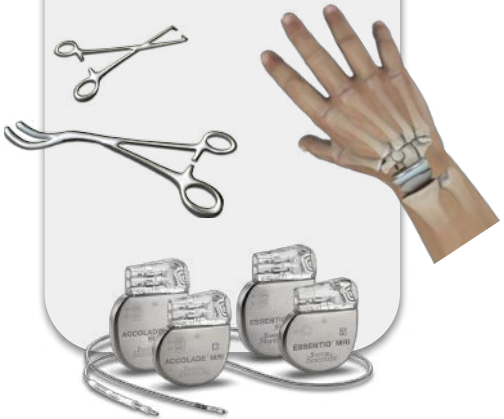
Applies to ***evaluation of materials*** and ***medical devices*** that are expected to have ***direct or indirect contact*** with –

Patient's Body



User's Body

Think about the product's..

Nature of Contact

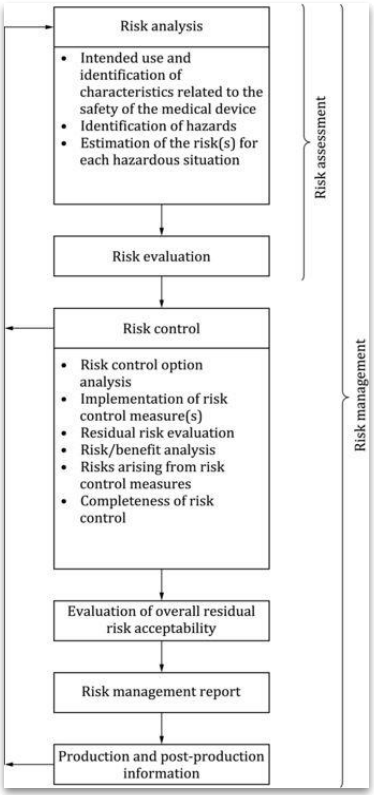
- → Non-contacting?
- → Surface only?
- → Externally communicating?
- → Implants?

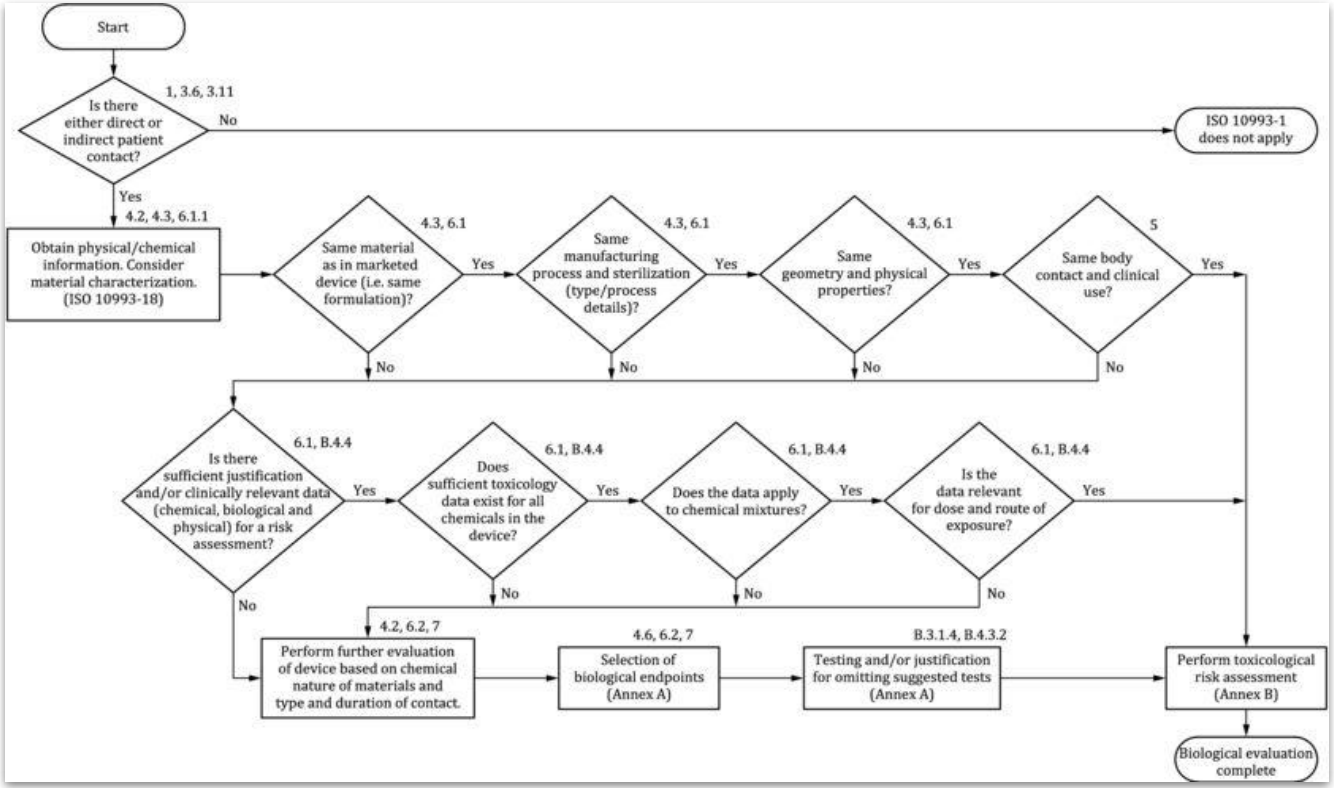
Duration of Contact

- → Upto 24 hrs?
- → 24 hrs - 30 days?
- → > 30 days?
- → Transitory contant?

Main Prescriptions: Biological Evaluation and Risk Analysis

ISO 10993





Main Prescriptions: Biological Tests

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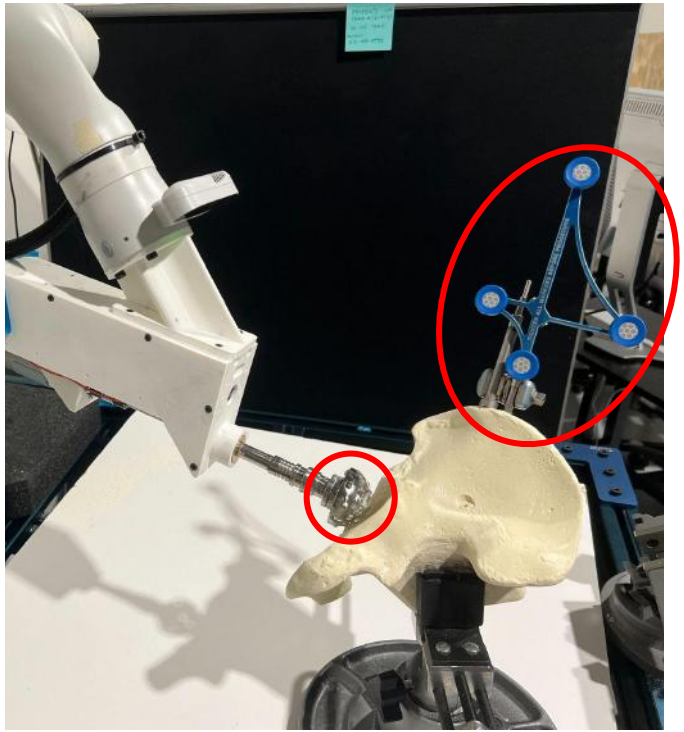
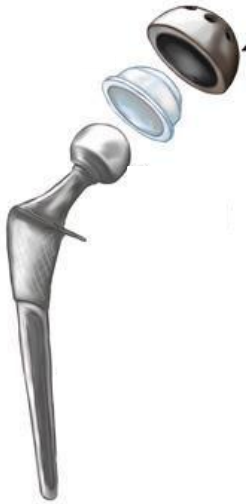
Medical device categorization			Biological Evaluation Tests													
Nature of contact		Contact duration	Information	Cytotoxicity	Sensitization	Irritation	Pyrogenicity	Acute toxicity	Subacute toxicity	Chronic toxicity	Implantation	Hemocompatibility	Genotoxicity	Carcinogenicity	Reproductive	Degradation
Category	Contact															
Surface medical devices	Intact skin	< 24 hour	X	X	X	X										
		< 30 days	X	X	X	X										
		> 30 days	X	X	X	X										
	Mucosal membrane	< 24 hour	X	X	X	X										
		< 30 days	X	X	X	X		X	X		X					
		> 30 days	X	X	X	X		X	X	X	X		X			
	Breached or compromised surface	< 24 hour	X	X	X	X	X	X								
		< 30 days	X	X	X	X	X	X	X		X					
		> 30 days	X	X	X	X	X	X	X	X	X		X	X		
Externally communicating medical device	Blood path, indirect	< 24 hour	X	X	X	X	X	X				X				
		< 30 days	X	X	X	X	X	X	X			X				
		> 30 days	X	X	X	X	X	X	X	X	X	X	X	X		
	Tissue/bone/ dentin	< 24 hour	X	X	X	X	X	X								
		< 30 days	X	X	X	X	X	X	X		X					
		> 30 days	X	X	X	X	X	X	X	X	X		X	X		
	Circulating blood	< 24 hour	X	X	X	X	X	X				X				
		< 30 days	X	X	X	X	X	X	X		X	X				
		> 30 days	X	X	X	X	X	X	X	X	X	X	X	X		
Implant medical device	Tissue/bone	< 24 hour	X	X	X	X	X	X								
		< 30 days	X	X	X	X	X	X	X		X					
		> 30 days	X	X	X	X	X	X	X	X	X		X	X		
	Blood path, indirect	< 24 hour	X	X	X	X	X	X			X	X				
		< 30 days	X	X	X	X	X	X	X		X	X				
		> 30 days	X	X	X	X	X	X	X	X	X	X	X	X		

Application to ARTHuR





Components to test for biocompatibility:

- Reamer head (stainless steel)
- Marker holder (stainless steel)
- Probe (stainless steel)

Other potential considerations for THR:

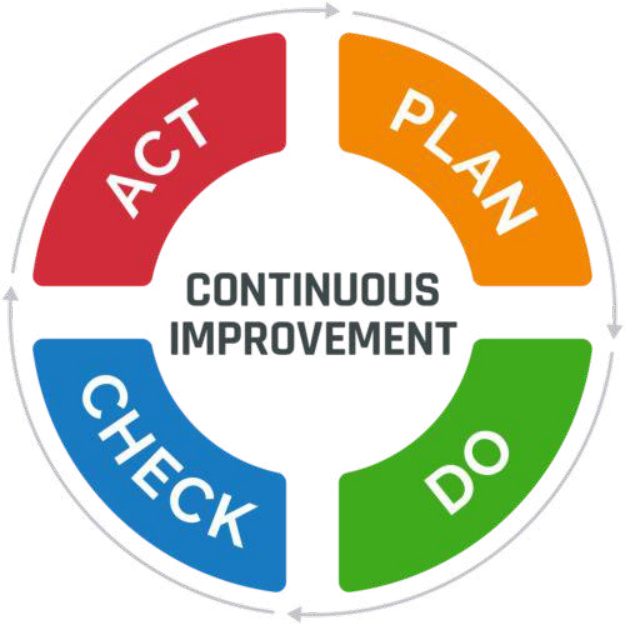
- Femoral stem (coarse titanium)
- Acetabular cup (coarse titanium)
- Bone screws (stainless steel)
- Femoral head (ceramic)
- Inner acetabular cup (polyethylene)

ISO 13485

Medical devices — Quality Management Systems

What is it about?

- A quality management system (QMS) is a **set of policies, processes and procedures** that help an organization meet the requirements expected by its stakeholders.
- ISO 13485 is designed to be used by organizations **throughout the life cycle of a medical device**, from initial conception to production and post-production, including final decommission and disposal.



Product Application

- **Conceptualization → Production → Post-production → Decommission → Disposal**
  - It also covers aspects such as storage, distribution, installation and servicing, and the provision of associated services.
- The standard **can be used by internal and external parties**, such as certification bodies, to help them with their certification processes, or by supply chain organizations that are required by contract to conform.
- Applicable to a wide range of medical equipment such as **wound dressings, implantable devices, and software controlled devices such as CT scanners etc**.

Main Prescriptions: General Requirements

- The organization shall
  - document a QMS and maintain its effectiveness
  - Apply a risk based approach to the control of the appropriate processes
  - Determine the sequence and interaction of these processes
- When the organization chooses to outsource any processes, it shall monitor and ensure control over such processes
- The organization shall document procedures for the validation of the application of computer software used in the quality management system

Main Prescriptions: Documentation Requirements

The quality management system documentation shall include:

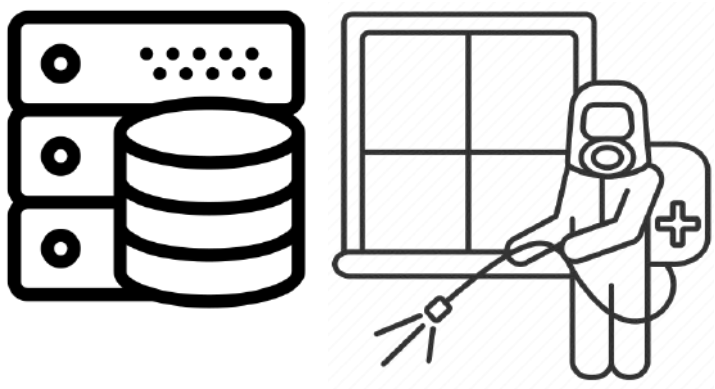
a) documented statements of a quality policy and quality objectives;
b) a quality manual;
c) documented procedures and records required by this International Standard;
d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation, and control of its processes;
e) other documentation specified by applicable regulatory requirements.

Main Prescriptions: Management Responsibility

- Top management **commitment**
  - Evidence of development, evidence and maintenance of QMS
- Ensuring customer **requirements development** & compliance
- Planning to **establish quality standards** at all levels & functions
- **Responsibility, authority and communication**
  - Personnel who have authority to ensure compliance with quality standards
  - Reports structure
  - Appropriate communication structure to ensure traceability of issues
- **Procedures for management reviews**
  - System to get reviews at all levels
  - Protocols for remedial outputs

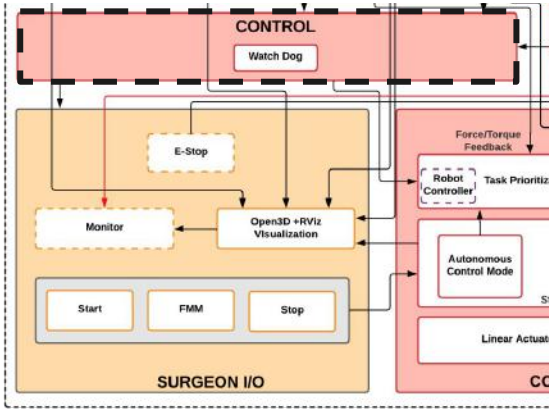
Main Prescriptions: Resource Management

- **Human resources**
  - Training, skills & experience
  - Evaluate efficacy
  - Maintain records of procedures undertaken
- **Infrastructure**
  - Buildings & workspaces
  - Equipment for quality measurement
  - Supporting physical & digital services
- **Work environment and contamination control**
  - Protocols for health, cleanliness and clothing of personnel
  - Sterilization



Application to ArTHUR

- **Project Planning**
  - Requirements development, documentation, and maintenance
  - Trade studies
  - Customer interviews & expert consultation with surgeons
- **Project management efforts**
  - Documentation control
  - Clear ownerships & accountability
  - Customer meetings and progress reviews
  - Issue logs and code reviews
- **System Validation and Verification**
  - Exposing key system health & performance parameters
  - Evaluation metrics for each sub-system at various stages
  - Active watchdog sub-system for continuous monitoring & intervention
- **Controlled work environment**, contamination control protocols, testing in later stages



i am biocompatible r u?

thanks!!!! ask me questions now.