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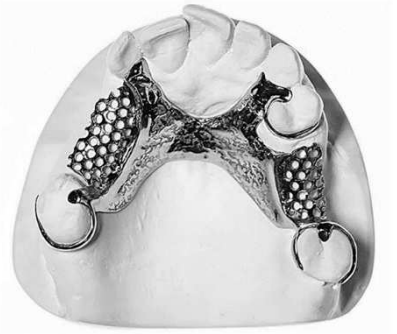
m4m

Initial considerations to 3D print in a certified MedTech environment.

researchXchange Seminar / IEEE

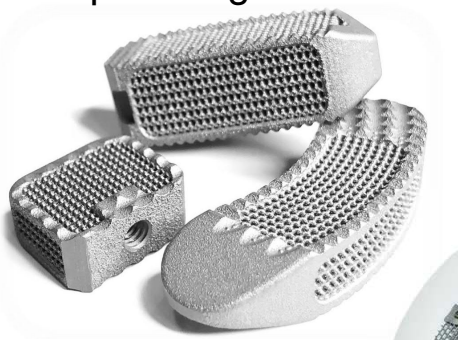
MedTech Additive Manufacturing

Example of Metallic Use Cases



removable denture

spine cages



custom cranial implant

bone reamer

acetabulum cup

Opportunities

- Individualization (lot size one)
- Short Lead Time
- Manufacturing of Complex Shapes
- Anatomical Shape
- Improved properties and functionalities

Challenges

- Adapted design strategy
- Control of process parameters
- Surface finishing and cleaning
- Initial Investments

Acetabulum Cup

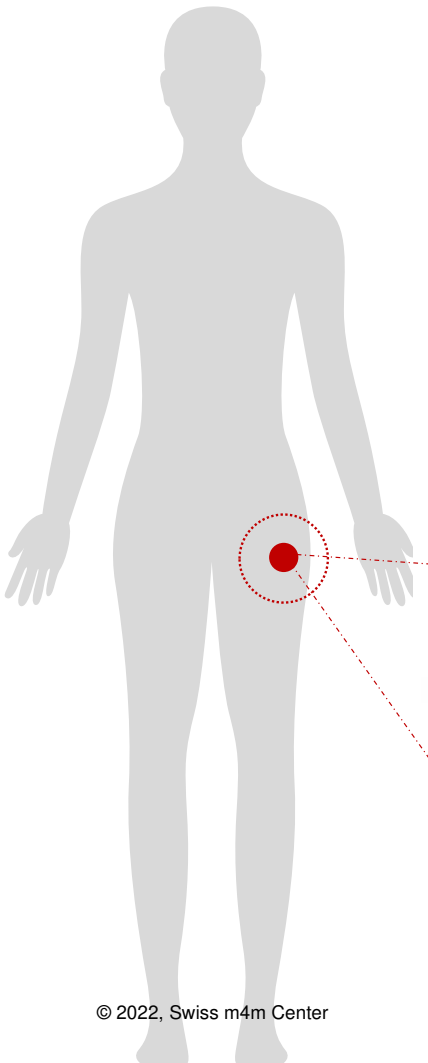
Acetabular cup with lattice structure used in total hip replacement (THR) surgeries or hip revision surgeries. The polyethylene or ceramic inlay is fixed in the inner cup geometry.

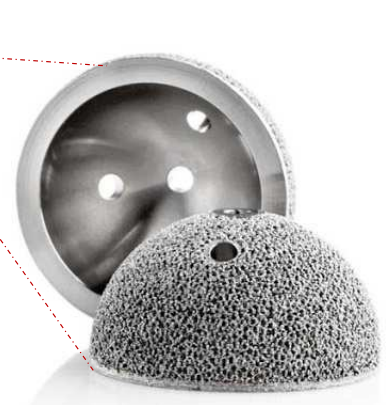
Material: Ti-6Al-4V Grades 5 and 23 (ELI), ASTM F136

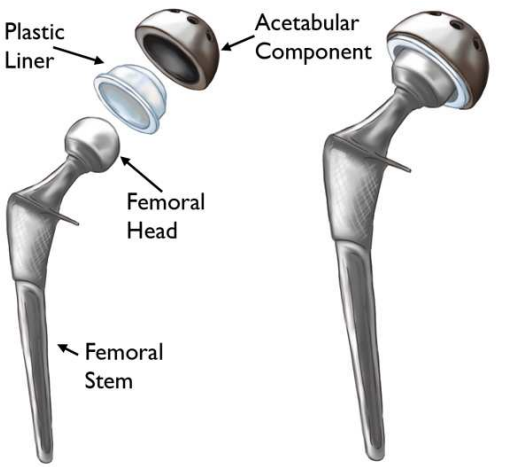
Process: Electron Beam or SLM, post processing

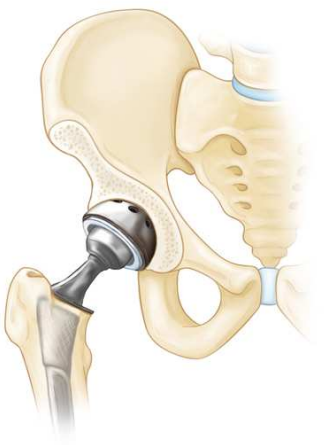
Regulatory Pathway: Non-active implant class III

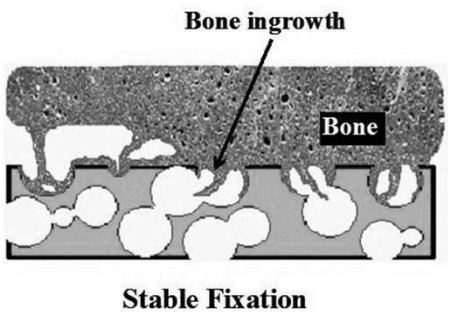
Implant functionality: Load carrier and bone ingrowth promoter

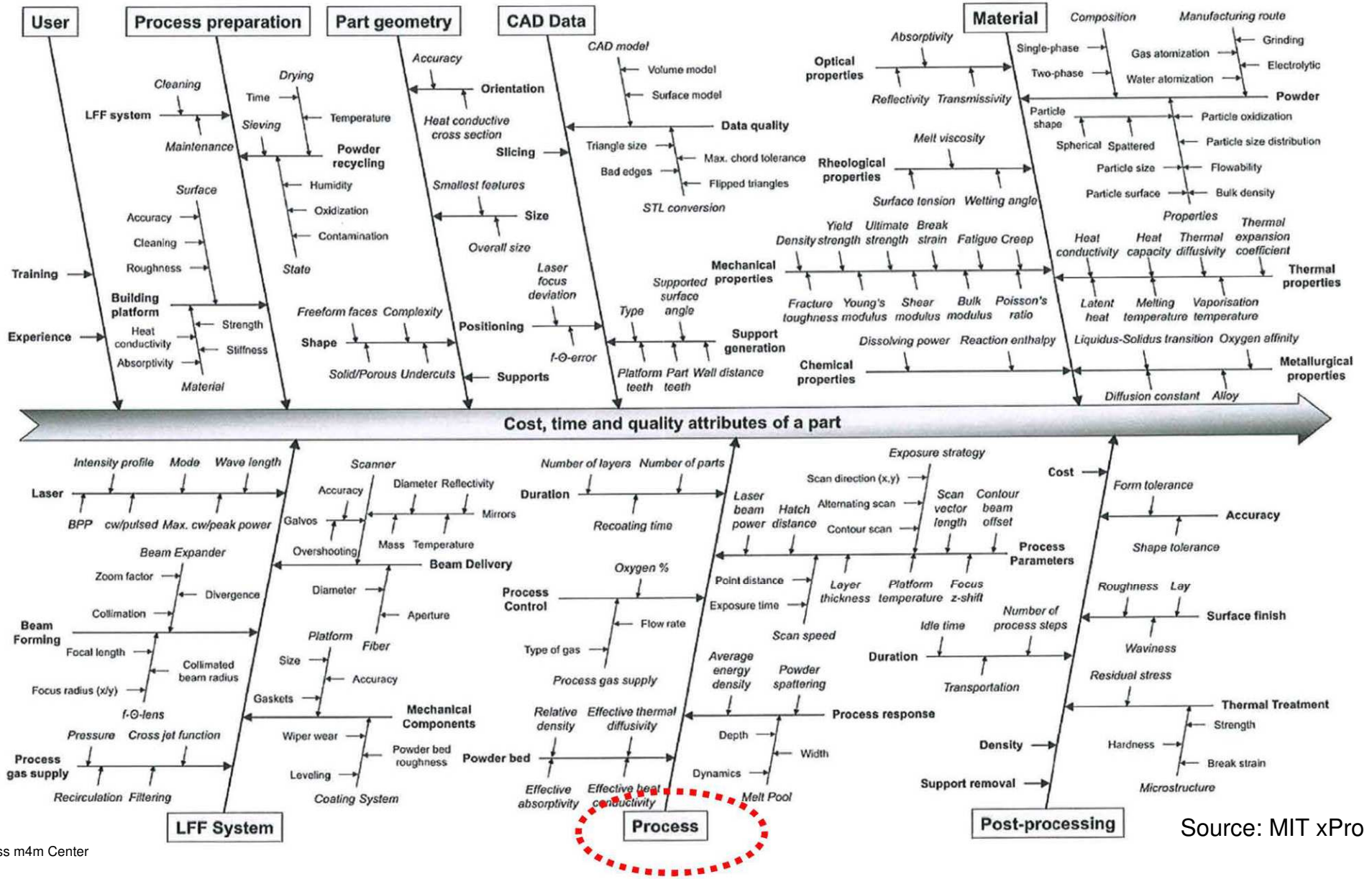






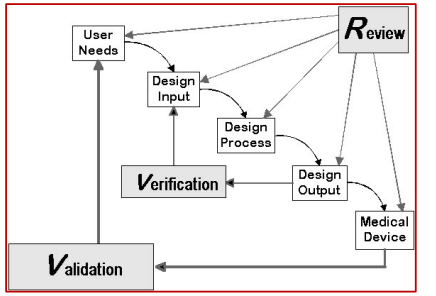


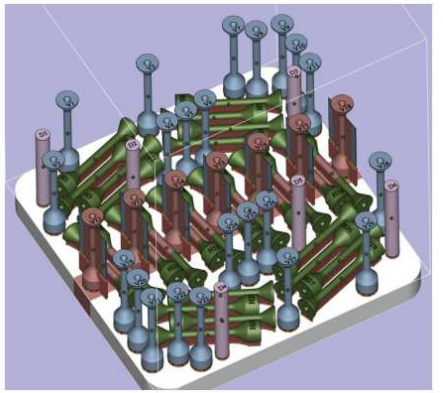


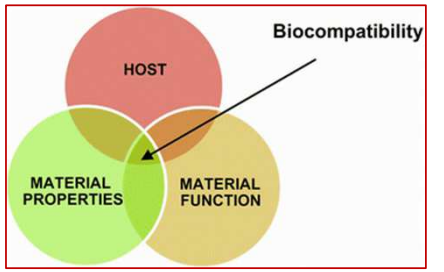


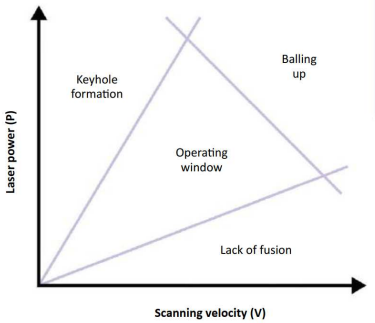
Source: MIT xPro

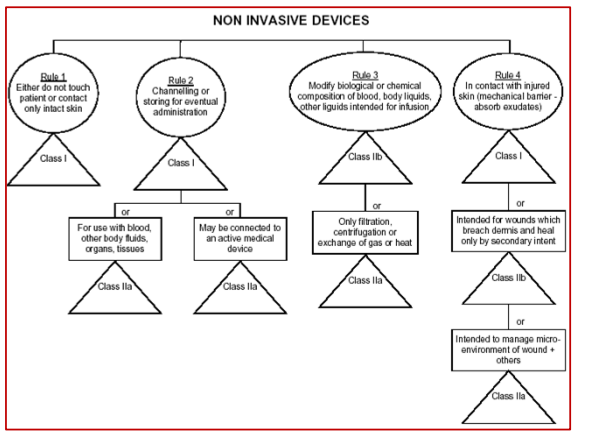
Some Considerations

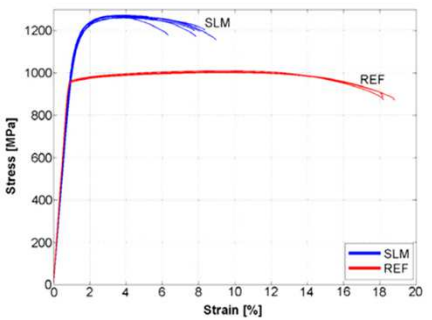


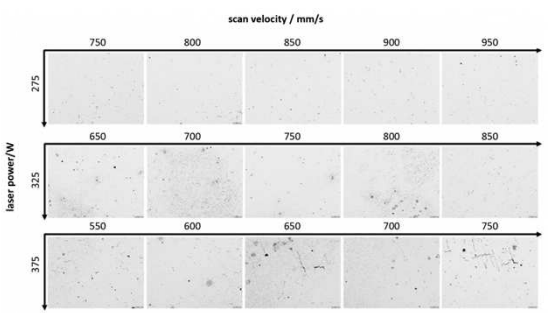


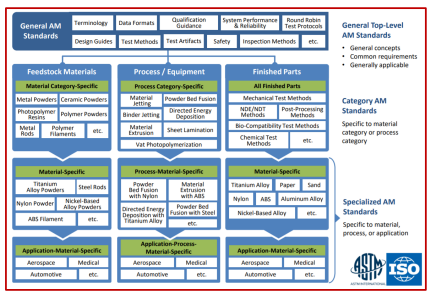












ISO 13485

ISO 13485 is a standard defining the aspects of a Quality Management System (QMS) for medical devices.

Depending on the service you are providing is specific to the medical device industry, ISO 13485 might appropriate to be implemented.
It is also about building trust in the MedTech Industry.

Ref: https://www.avanti-europe.ch/who-needs-to-get-certified-according-iso-13485/
https://www.sourcebioscience.com/news/iso-90012015-quality-management-system-qms/

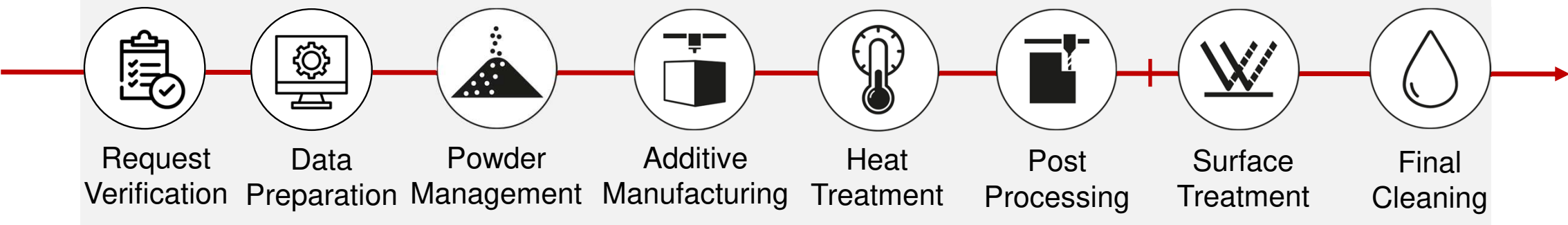
Production under ISO 13485

End to End process chain.

ISO 13485:2016

Spine	CMF Dental	Orthopedics	Cardiology	Instruments	Others

Pre Processing | In Processing (Validated) | Post Processing (Validated)



Qualified Suppliers

Manufacturing MedTech AM Route

AM has to be integrated into a supply chain under a defined QMS

1) Powder inspection
2) Data preparation
3) Build job (Additive Manufacturing)
4) Unpacking / (de-powdering)
5) Heat treatment / Pressing
6) Support removal / post machining
7) (Hot isostatic pressing)
8) Sand blasting / vibration grinding
9) Surface treatment / Polishing
10) Laser marking
11) Cleaning
12) Sterilization

Quality Management System: ISO 13485

Internal and external processes

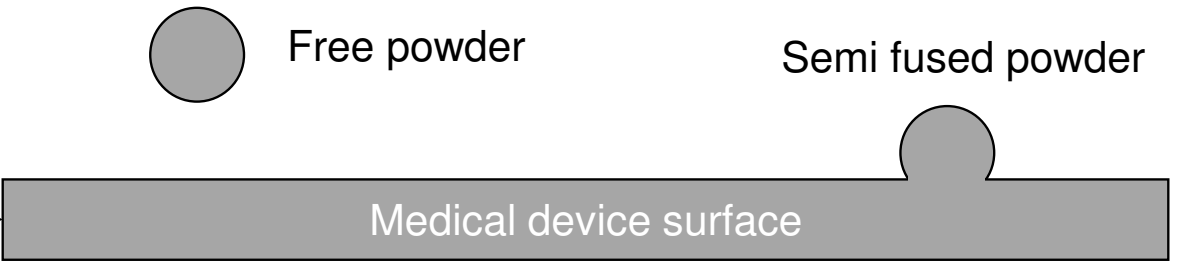
A Different Risk Perspective

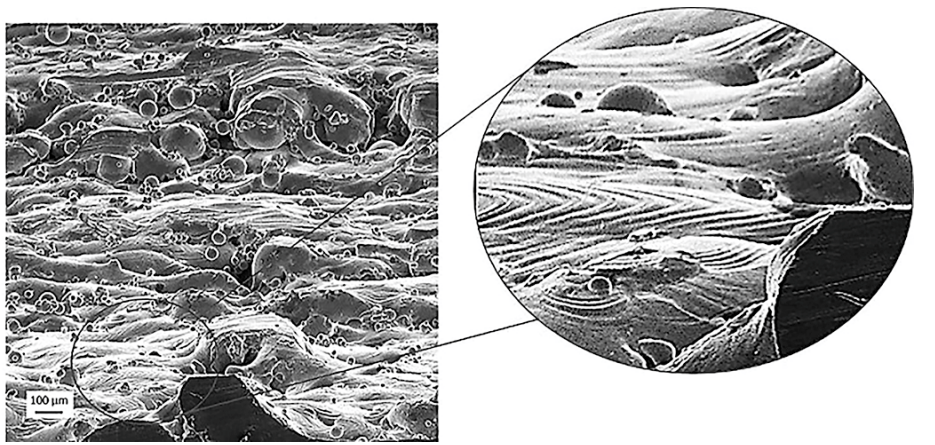
Starting from a bar of metal, we use a CNC equipment to remove material until we obtain the right dimensions.
The subtractive process is well know, the risks as well.
Mitigation measures are in place

For 3D printing, everything is built from a powder. What is inside the part cannot be inspected.
The remaining questions are: “Did the laser power really melted the metal on all the layer? Is this reliable and reproducible?”

Validation activity should now see the process in a different way than a CNC process. The parameters are different and the risks are also different.

Unpacking / Depowdering…





Production Qualification

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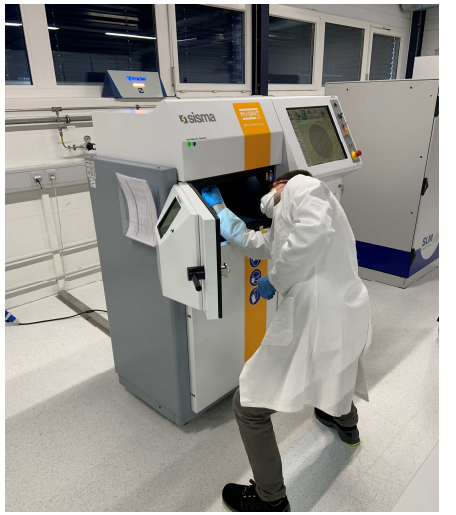
1) Machine Qualification

IQ: Installation Qualification
OQ: Operational Qualification
PQ: Performance Qualification

2) Working Instruction

Personnel Qualification
SOP: Standard Operating Procedures
Checklists



3) Process Validation

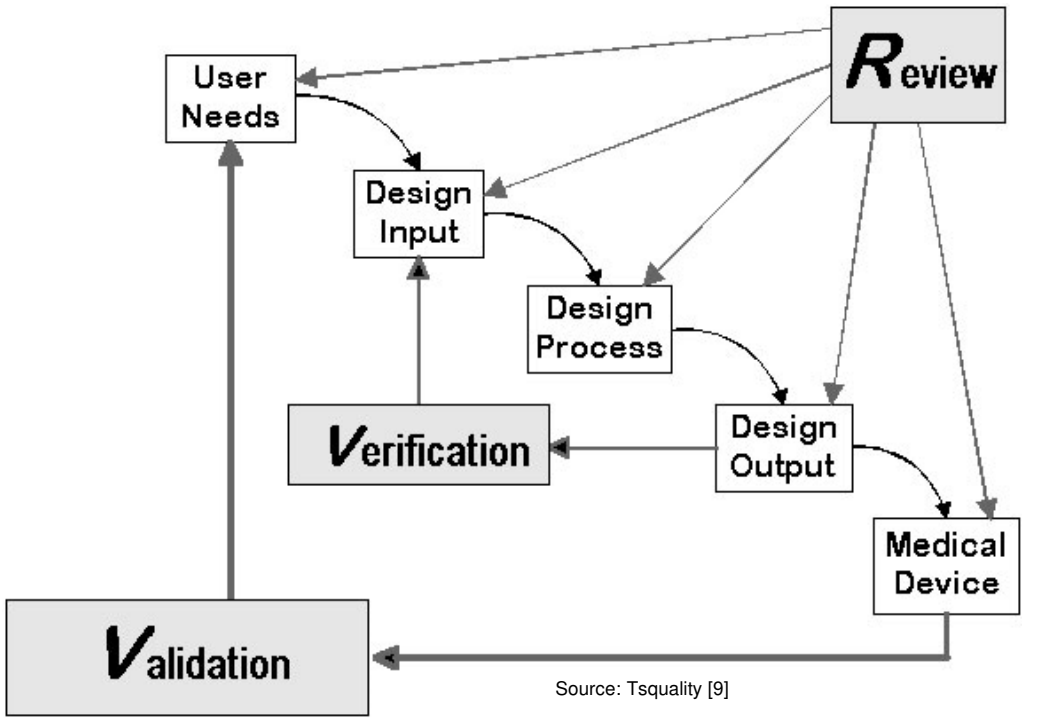
AM
Post-processing
…

ASTM ISO/ASTM52930-21: Guide for Additive manufacturing – Installation/Operation and Performance Qualification (IQ/OQ/PQ) of Laser-Beam Powder Bed Fusion Equipment for Production Manufacturing.

V&V and ISO 13485

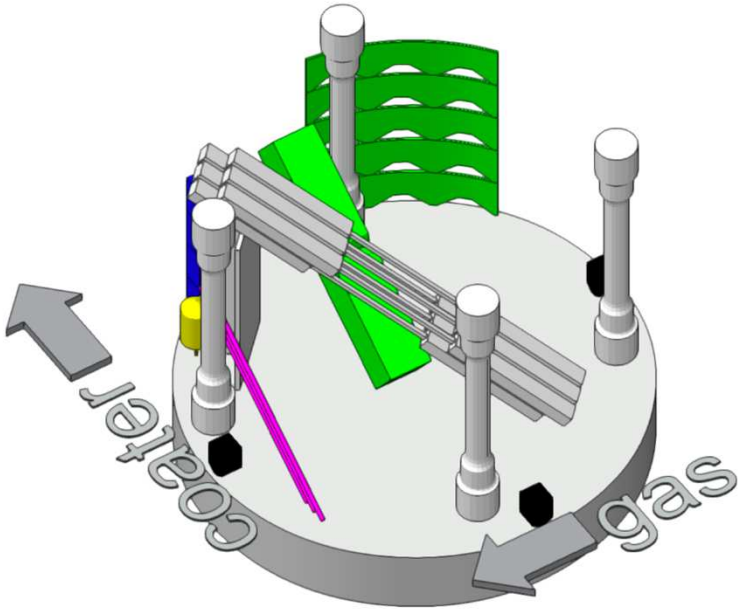
In the MedTech filed, validation is part of the Norm ISO 13485.

Under the clause 7.5.6, EN ISO 13485 mandates that organizations validate those processes for which verification is not possible.



Source: Tsquality [9]

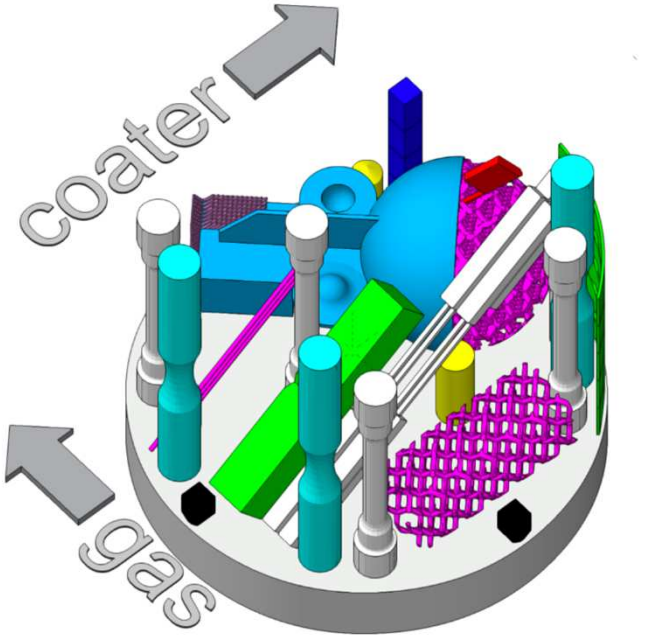
OQ / PQ Runs @ m4m



OQ Build Jobs

8 worst case runs

Min / Max investigation

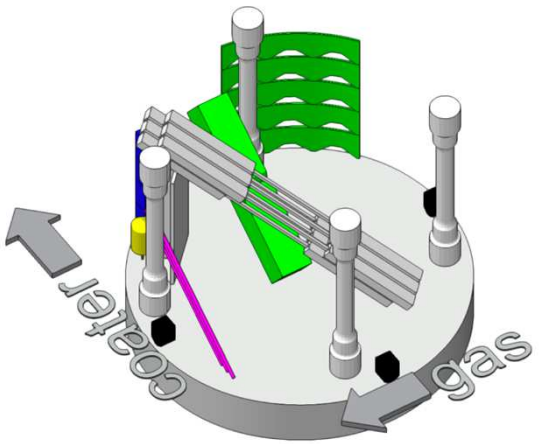


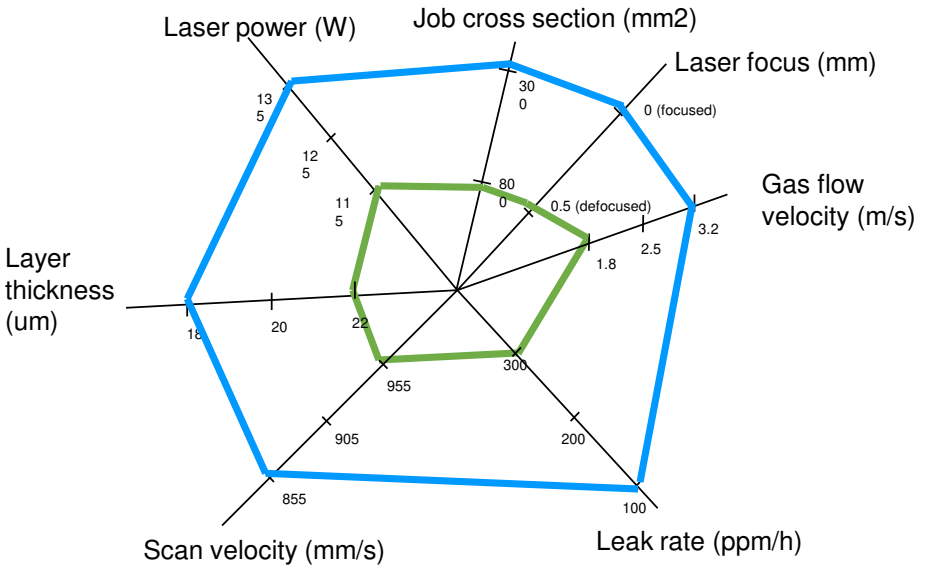
PQ Build Jobs

30 nominal runs

Consistency / powder degradation

OQ Runs: Min / Max Definition

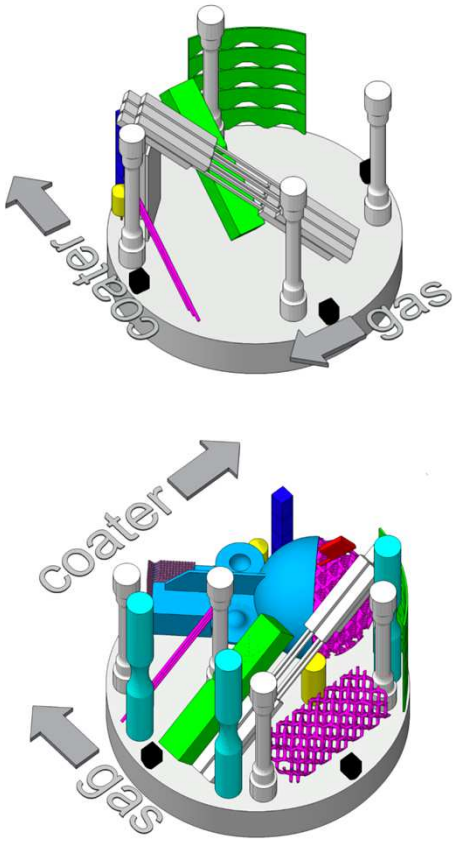




Minimum energy density

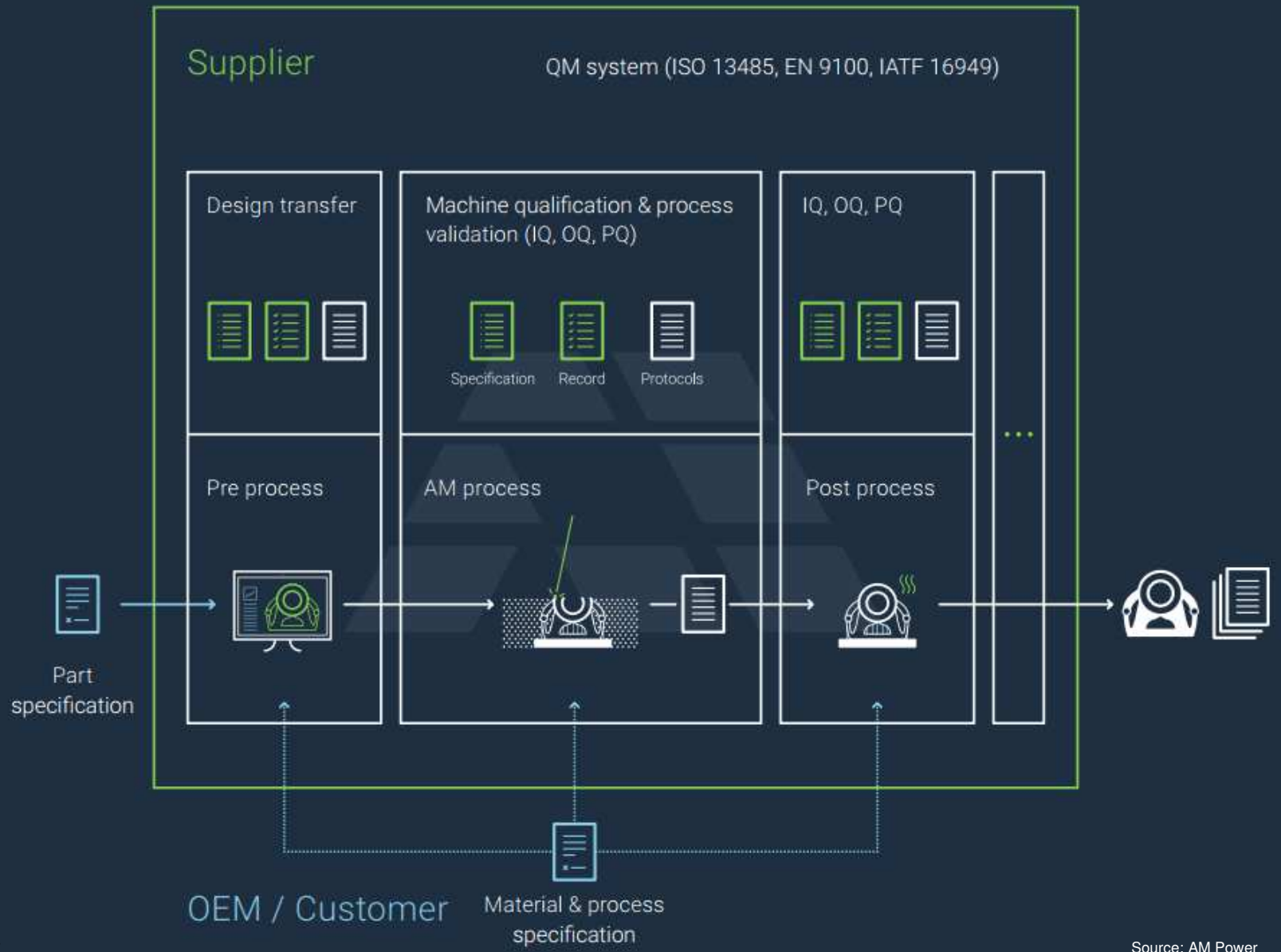
Maximum energy density

OQ / PQ Runs @ m4m



OQ / PQ runs

Acceptance Criteria	Topic
ASTM B348-B348M	Material (TI64)
ASTM F136	Material (TI64)
ASTM F899	Material (SST)
ISO 10993	Biocompatibility
…	



Center

Source: AM Power

Material Qualification

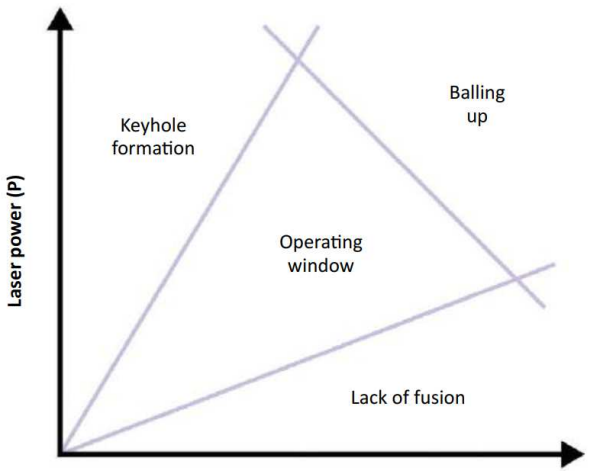
Energy density is used as base for material qualification. Density and mechanical performance are defined as testing criteria.

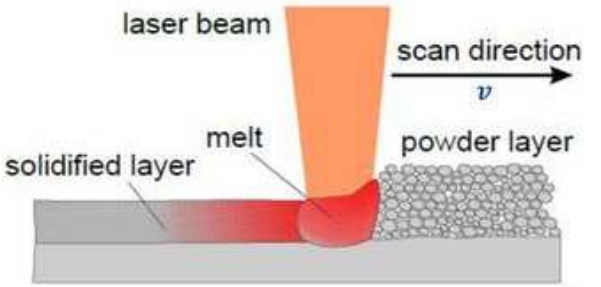
L: laser power
v: scan velocity
Δy: hatch distance
Δz: layer thickness

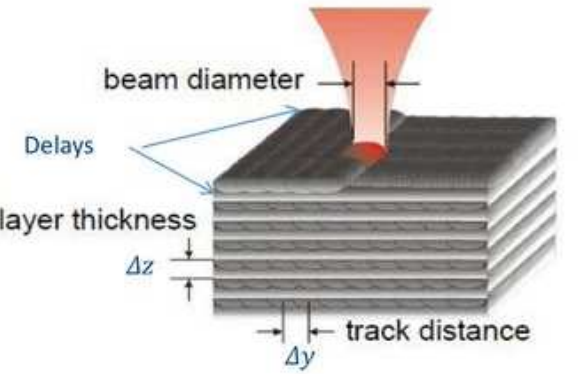
$$E_d = \frac{P_{laser}}{v_{scan}\Delta_{hatch}h_{layer}} \left[\frac{J}{m^3}\right]$$

Energy Density $E = L/(v \times \Delta y \times \Delta z)$

Build Rate: $V = v \times \Delta y \times \Delta z$







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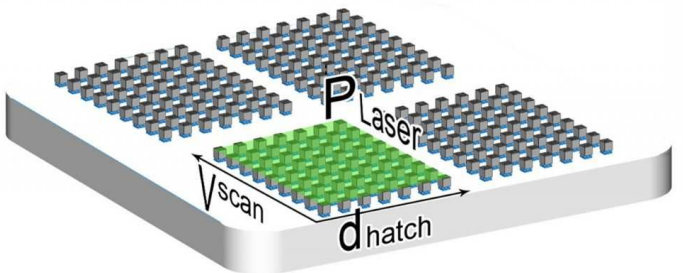
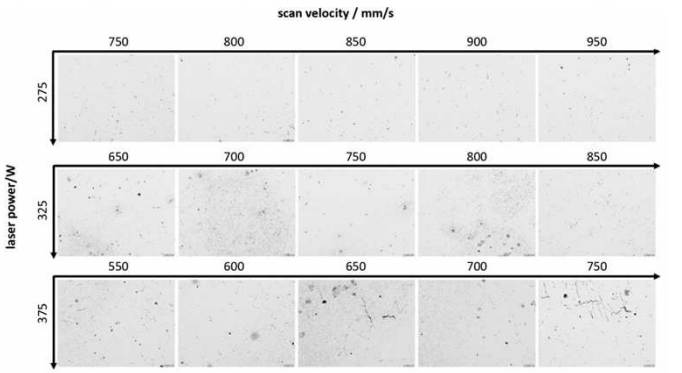
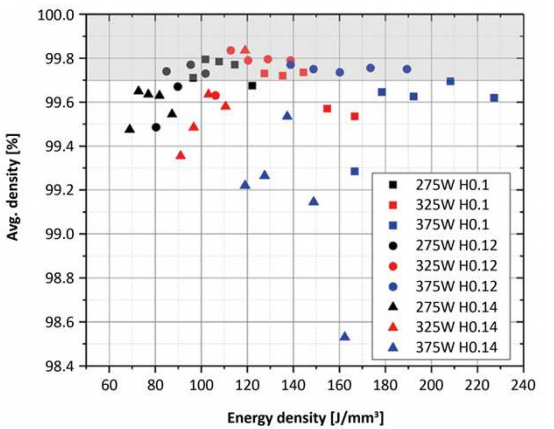
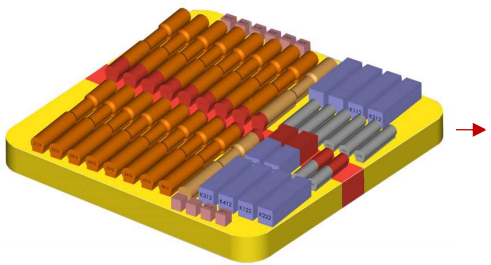




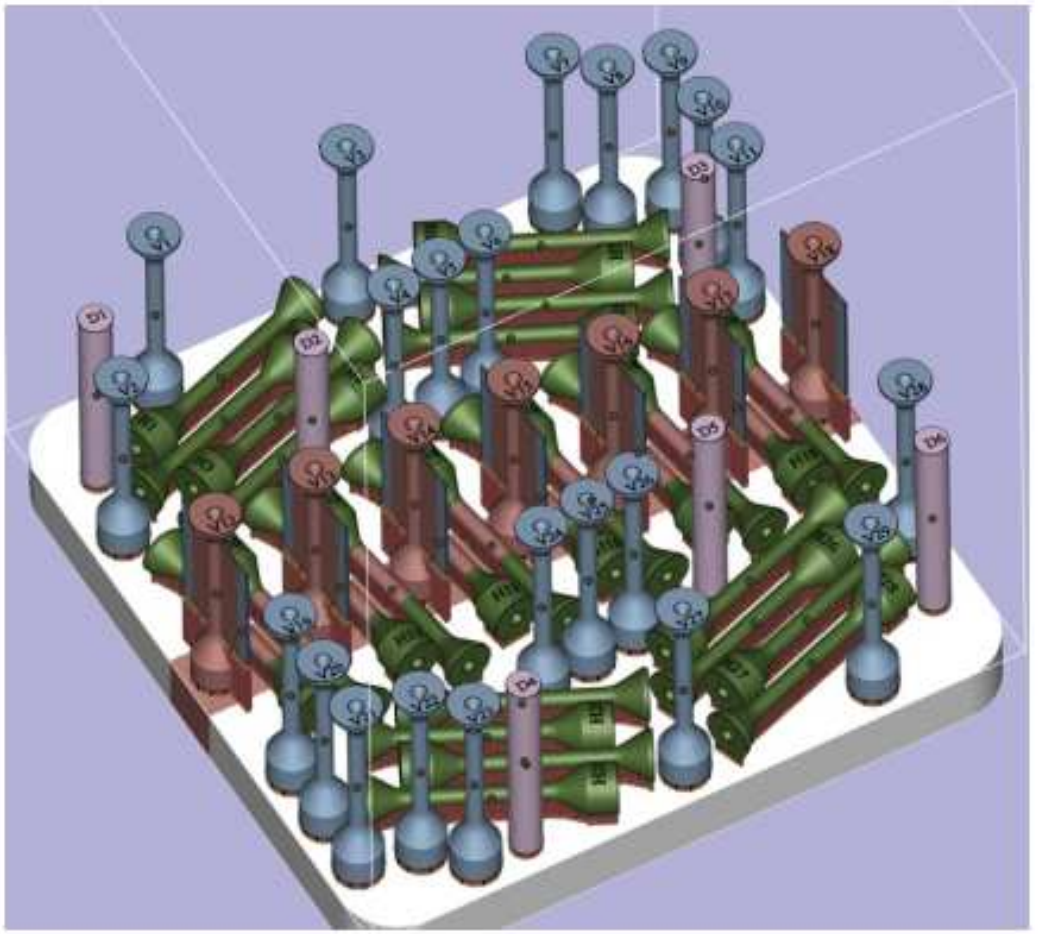




Standards Requirements

Ref: Metal Additive Manufacturing | Summer 2019, P.159

Machine Acceptance Build Job



Source: SLM

Biocompatibility Assessment

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Testing and Evaluation Strategies for the Biological Evaluation of Medical Devices submitted for CE Mark and FDA Approval

Table 1: ISO 10993-1 Biocompatibility Testing Selection Criteria

Medical device categorization by			Biological Effect [a]							
Nature of body contact		Contact duration								
Category	Contact	A - limited (≤ 24 h) B - prolonged (> 24 h to 30 d) C - permanent (> 30 d)	Cytotoxicity	Sensitization	Irritation or intracutaneous reactivity	Systemic toxicity (acute)	Subchronic toxicity (subacute toxicity)	Genotoxicity	Implantation	Haemocompatibility
Surface device	Skin	A	X	X	X					
		B	X	X	X					
		C	X	X	X					
	Mucosal membrane	A	X	X	X					
		B	X	X	X					
		C	X	X	X		X	X		
	Breached or compromised surface	A	X	X	X					
		B	X	X	X					
		C	X	X	X		X	X		
External communicating device	Blood path, indirect	A	X	X	X	X				X
		B	X	X	X	X				X
		C	X	X		X	X	X		X
	Tissue/bone/ dentin	A	X	X	X					
		B	X	X	X	X	X	X	X	
		C	X	X	X	X	X	X	X	
	Circulating blood	A	X	X	X	X				X
		B	X	X	X	X	X	X	X	
		C	X	X	X	X	X	X	X	
Implant device	Tissue/bone	A	X	X	X					
		B	X	X	X	X	X	X	X	
		C	X	X	X	X	X	X	X	
	Blood	A	X	X	X	X	X		X	X
		B	X	X	X	X	X	X	X	X
		C	X	X	X	X	X	X	X	X

Note:
a The "X" indicates data endpoint that can be necessary for a biological safety evaluation, based on a risk analysis. Where existing data are adequate, additional testing is not required.

Testing to make sure the 3D printed materials are safe to use in conjunction with the human body and medical procedures.

Table 1. ISO 10993-1, simplified by UL.

Ref: https://blog.trimech.com/fdm-material-biocompatibility#:~:text=What%20is%20Biocompatibility%3F,accessory%20to%20the%20medical%20process.

Medical Device Classification (MDR)

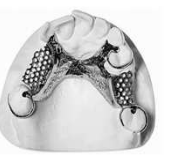
	Self	Notified body			
Examples	Wheelchair Otoscope Scalpel Plaster	Reprocessed Measuring function Delivered sterile	Syringe Teeth implant X-Ray device Tracheotomy tube	Blood bag Implantable plate Condoms	Drug coated stent Spinal disc cage Breast implants Pacemaker
Class	CLASS I	CLASS I special function	CLASS IIa	CLASS IIb	CLASSIII

M,R,S

Low — RISK — High





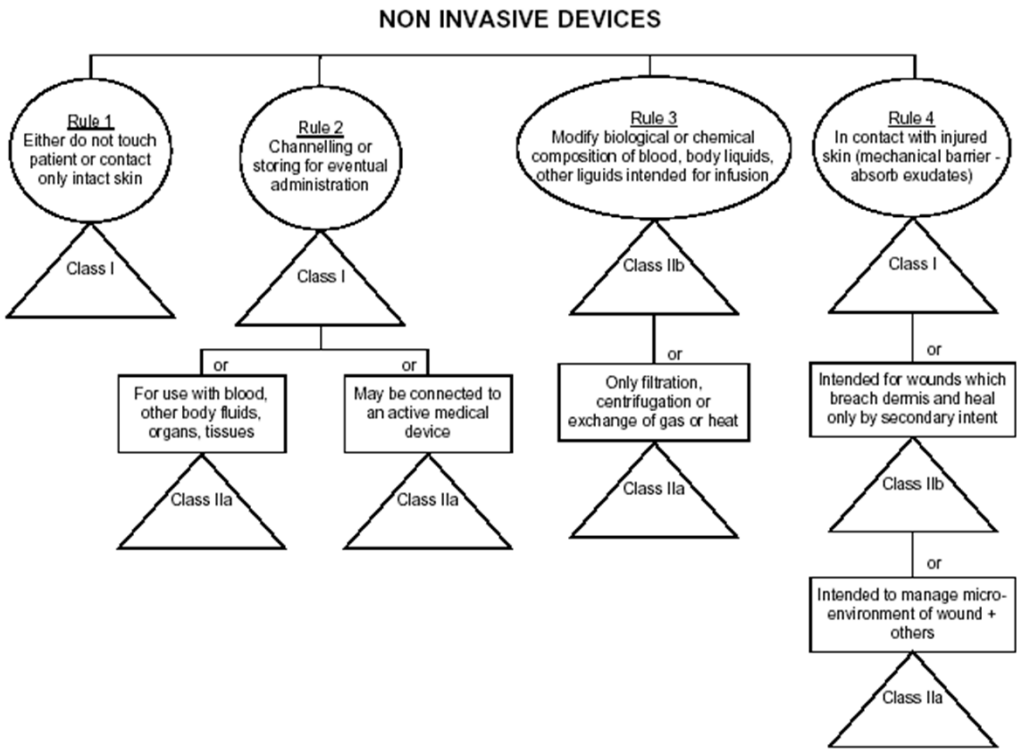


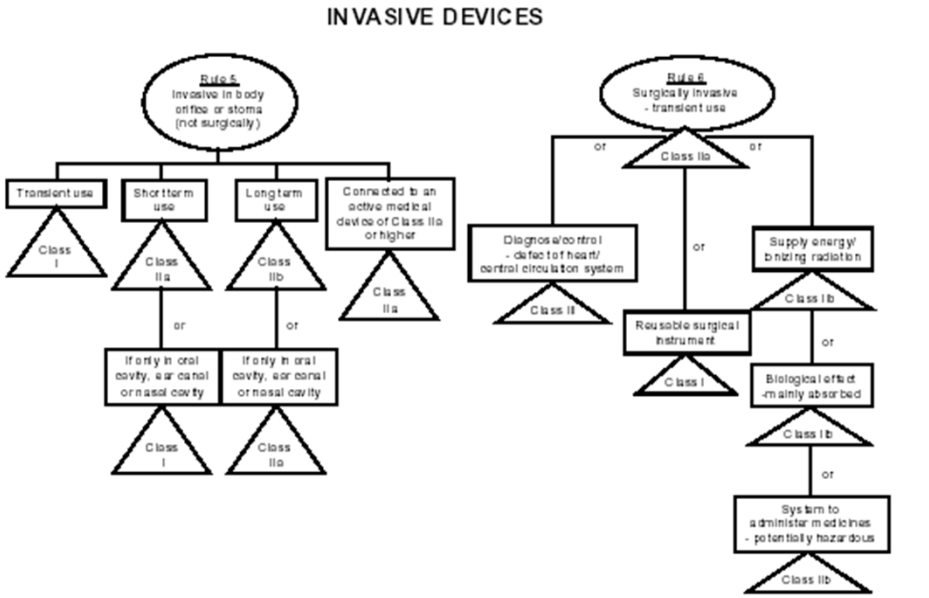

MD Classification (MDR)

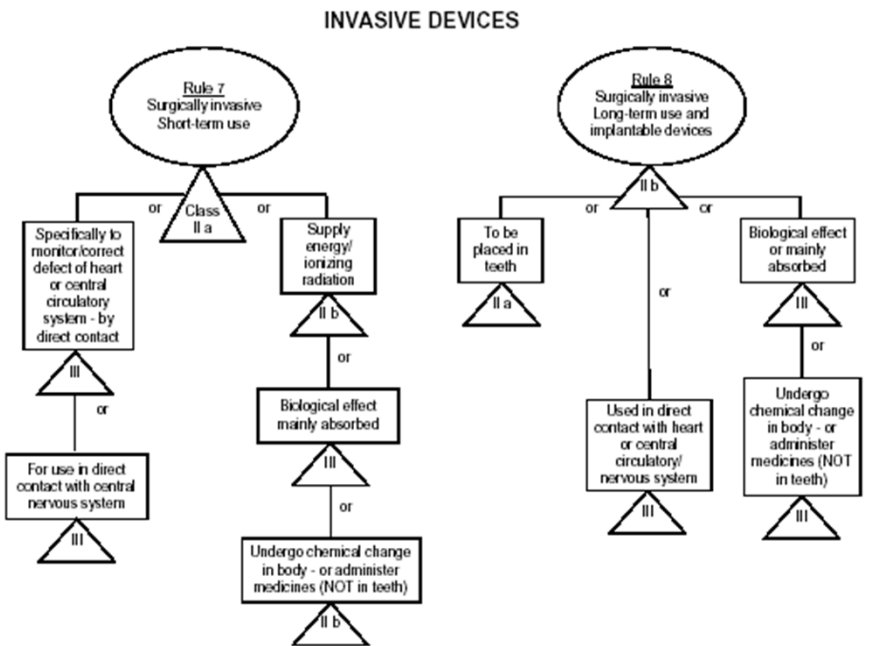
Classification of a medical device will depend upon a series of factors, including:

- how long the device is intended to be in continuous use
- whether or not the device is invasive or surgically invasive,
- whether the device is implantable or active
- whether or not the device contains a substance, which in its own right is considered to be a medicinal substance and has action ancillary to that of the device.

MD Classification (MDR)







ASTM F42 / ISO TC 261

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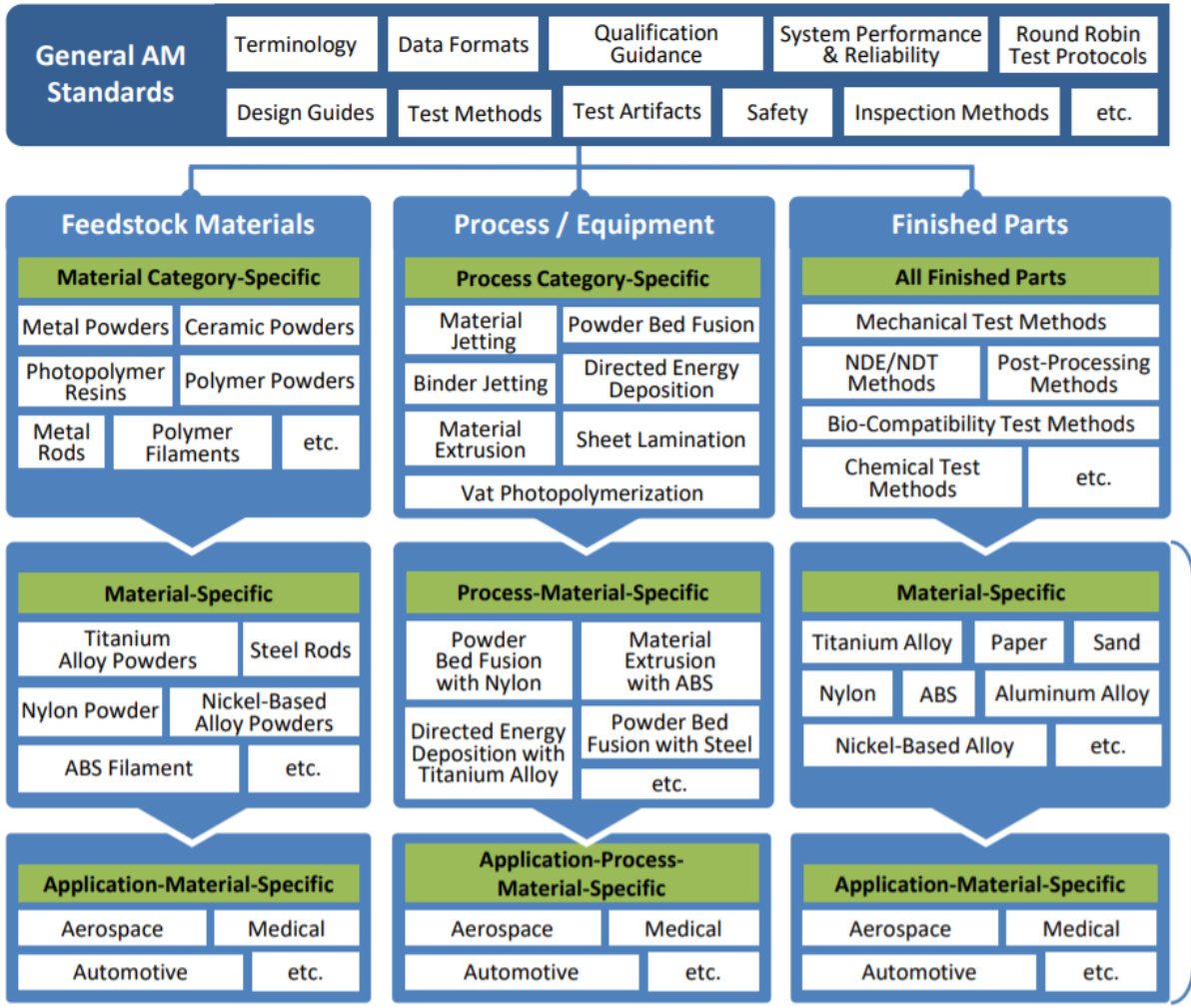

General Top-Level AM Standards

- General concepts
- Common requirements
- Generally applicable

Category AM Standards

Specific to material category or process category

Specialized AM Standards

Specific to material, process, or application

ASTM INTERNATIONAL

ISO

ASTM F42 / ISO TC 261

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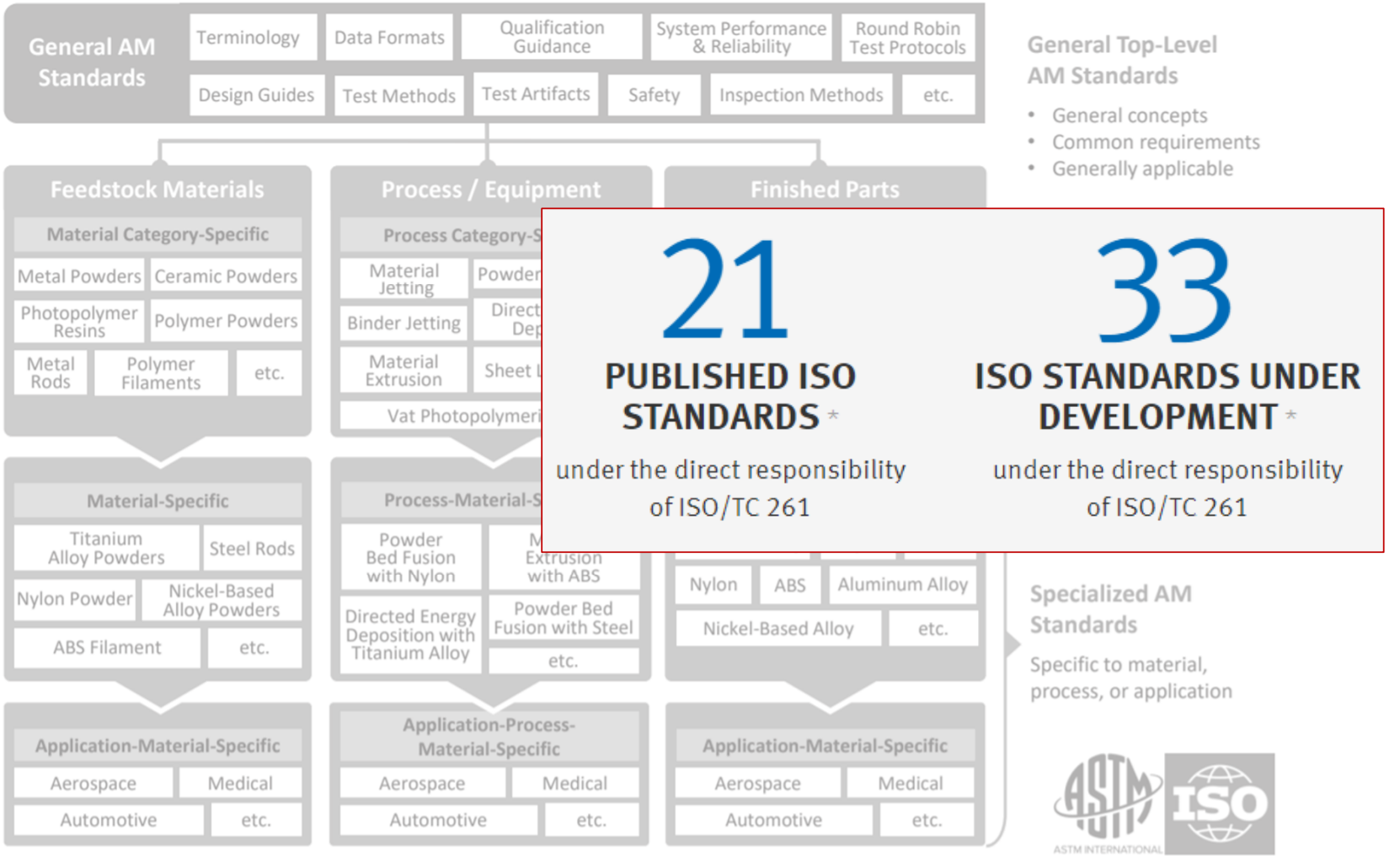

Production Infrastructure @m4m

Do you have any questions?

Swiss m4m Center AG
Föhrenweg 7
2544 Bettlach
+41 32 645 00 24
info@swissm4m.ch