SECTOR SKILLS STRATEGY IN ADDITIVE MANUFACTURING

Co-funded by the Erasmus+ Programme of the European Union

Project No. 601217-EPP-1-2018-1-BE-EPPKA2-SSA-B

CU 63: Certification, qualification and standards (2nd Stage Pilot)

Day 3 – Planning and executing CQS

Prepared by: David Wimpenny

Date: 09/05/21

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Welcome and plan for this final training session

- ~next 2 hours – presentations on implementing CQS

Then

Complete the end of course questionnaire

Under take the course assessment

You need to do both to ensure that you can be issued with a certificate for completion of the course

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Topics to covered today

- Quality management system – The framework
- Traceability & documentation – The foundation
- Impact of CQS on the business – Practical implications

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DAY 3
PART 1

3

09.00 TRAINING

~45 MINS

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Quality Management

- Quality management means what the organization does to;
  - ensure that its products or services satisfy the customer's quality requirements

  and
  - comply with any regulations applicable to those products or services (ie CQS).

REF: Overview of ISO 9001 and ISO 14001 by Roger Frost e-mail frost@iso.org Manager, Communication Services2009-01-08

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What is a Quality Management Systems (QMS) ?

"Collection of policies, procedures, plans, resources, processes, practices, and the specification of responsibilities and authority of an organization designed to achieve product and service quality levels, customer satisfaction and company objectives…"

It is an essential element to ensure that CQS is implemented and adhered to within an organisation

Ref:https://www.academia.edu/19670615/Dave_John_Mike_Quality_Management_Systems_PPT_03

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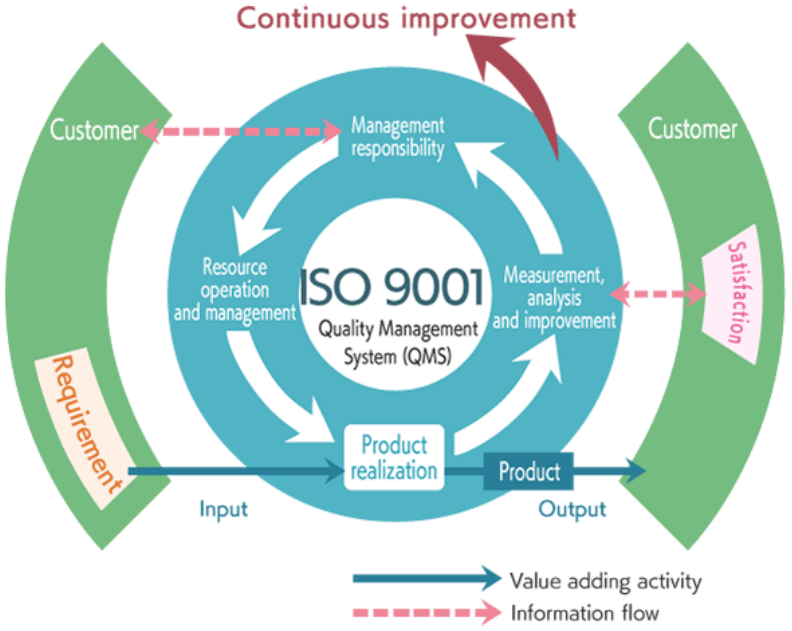
QMS Standards

Provide the organization with an international, state-of-the-art model to follow

ISO 9001 - quality management system industry generic

AS 9100 – quality management system for aviation space and defence



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Principles of the ISO 9001 Standard

1. Customer Focus
2. Leadership
3. Involvement of People
4. Process Approach
5. System Approach to Management
6. Continual Improvement
7. Factual Approach to Decision Making
8. Mutually Beneficial Supplier relationships

Ref:https://www.academia.edu/19670615/Dave_John_Mike_Quality_Management_Systems_PPT_03

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Quality System **Documentation** Overview

Documentation is critical to the implementation of QMS and is also critical for CQS

More detail towards the based of the QMS pyramid

https://advisera.com/9001academy/knowledgebase/how-to-structure-quality-management-system-documentation/

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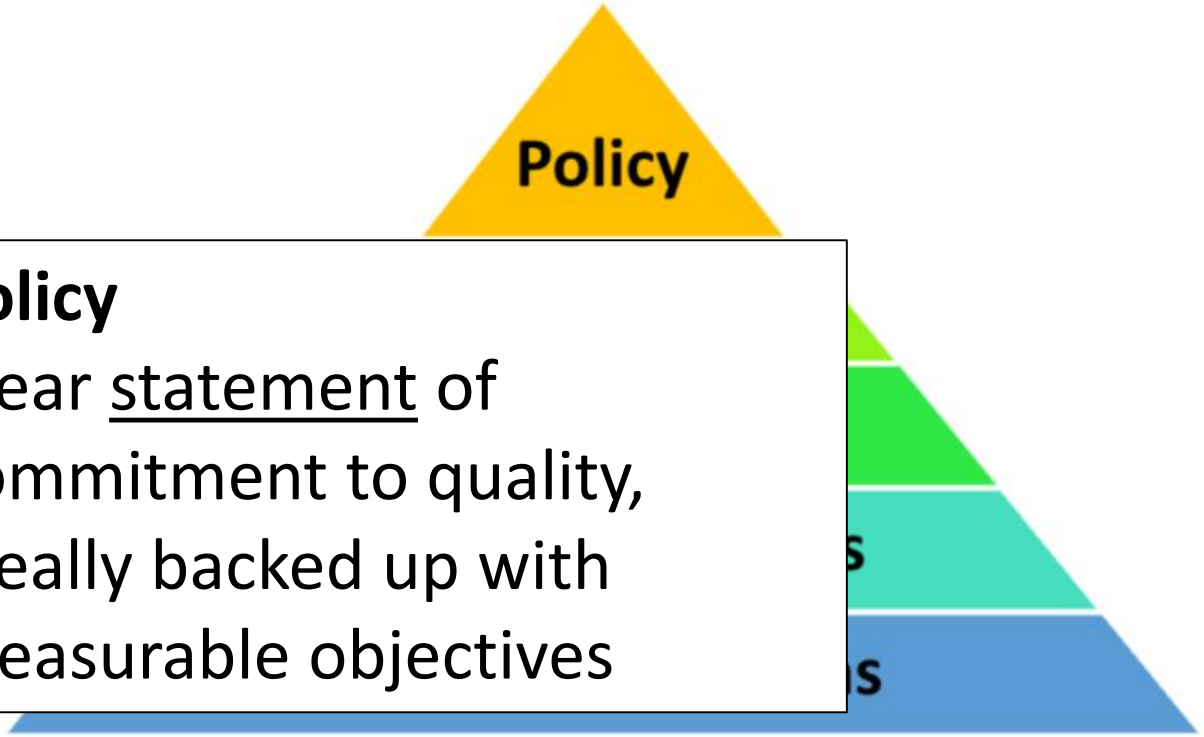
Quality System Documentation Overview



Policy
Clear statement of commitment to quality, ideally backed up with measurable objectives

https://advisera.com/9001academy/knowledgebase/how-to-structure-quality-management-system-documentation/

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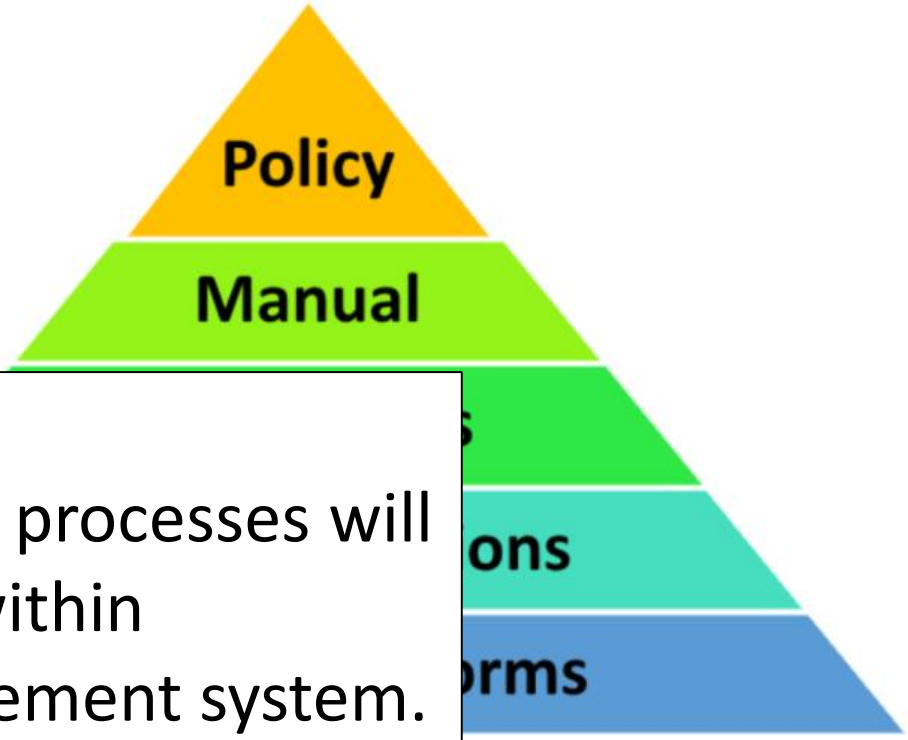
Quality System Documentation Overview



Manual

Describes how the processes will be implemented within the quality management system.

https://isoconsultantkuwait.com

edgebase/how-to-structure-
on/

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Quality System Documentation Overview

Procedures

Step by step what the company does to meet policy

- Procedure for each ISO principle
- Processes for procedures that affect quality

https://www.iso-9001-checklist.co.uk/quality-manual-template-gbp.htm

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Work Instructions

Document containing detailed instructions that specify exactly what steps to follow to carry out an Activity. A work instruction contains much more detail than a Procedure and is only created if very detailed instructions are needed

https://advisera.com/9001academy/knowledgebase/how-to-structure-quality-management-system-documentation/

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Quality System Documentation Overview

Records & Forms

- Proof of activities
- Documentation for auditors
- Ensure consistency of the firms operations
- Verify conformance to standards

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Traceability

- The foundation of CQS
- It is not enough to follow a process
- You need to be able to prove you followed it
- Particularly when something goes wrong !

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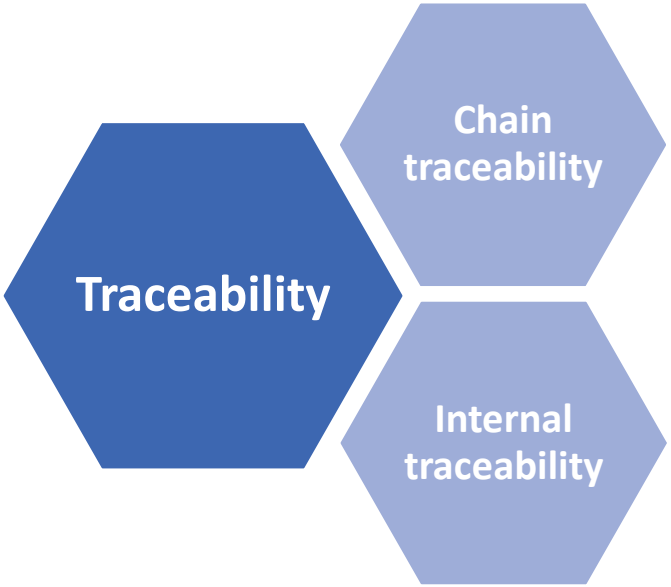
What is Traceability in Additive Manufacturing

- Covers all stages of AM process from feedstock procurement to production of AM parts, post processing, part testing, distribution or disposal need to be traceable.

- For an AM facility both **chain** (supply of goods/services from outside of the business) and **internal** traceability need to be considered



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Documentation for Traceability in AM

- Documentation of intended work
- Record Keeping of what has been done

mtc Powder Receipt Record Sheet

Op	Description					Comments
00	Request info from Originator	Copy of order info	☐			e.g. PO or email Required for Op 10
		Owner				Required for Op 20; Op 40; Op 50
		Specific uses				Required for Op 40; Op 50
		Project code				Required for Op 60; Op 61
10	Collect delivery from Goods In & compare delivery labelling against order info		Order Info	Delivery		Info required for Op 20; Op 40; Op 50 Operators must be manual handling trained Lifting aids may be required Knife may be required External Companies = Supplier and / or manufacturer
		Base material				
		Alloy				
		Nominal size (µm)				
		Date receipted				
		External company 1				
		External company 2				
		External batch ID				
11	Op 10 review gate	Powder Management	Accept / Flag	Initial		All info in Op 10 matches → Accept and go to Op 20 Any info in Op 10 does not match → Flag and go to Op 12
12	Op 11 flagged	PO Originator	Accept / Reject	Initial		Accept → Powder Management to continue from Op 20 Reject → Originator to contact supplier
20	Check whether validation testing is required (see Decision Workflow)	Is validation testing required?	Yes / No			Yes → Book into Quarantine No → Book into Storage
30	Book the delivery in		Order Info	Actual		
		Quantity	kg	kg		Required for Op 40; Op 50
		No of containers				Required for Op 40; Op 50
		Location	Storage / Quarantine			Refer to Op 20
		Inventory completed?	☐			
31	Op 30 review gate	Powder Management	Accept / Flag	Initial		Quantity in Op 30 matches → Accept and go to Op 40 Quantity in Op 30 does not match → Flag and go to Op 32
32	Op 31 flagged	PO Originator	Accept / Reject	Initial		Accept → Powder management to continue from Op 40 Reject → Originator to contact supplier
40	Assign MTC Batch ID and update powder tracker	MTC Batch ID	MTC _____			Required for Op 50
		Tracker updated?	☐			
50	Apply MTC labelling	Labelling completed?	☐			

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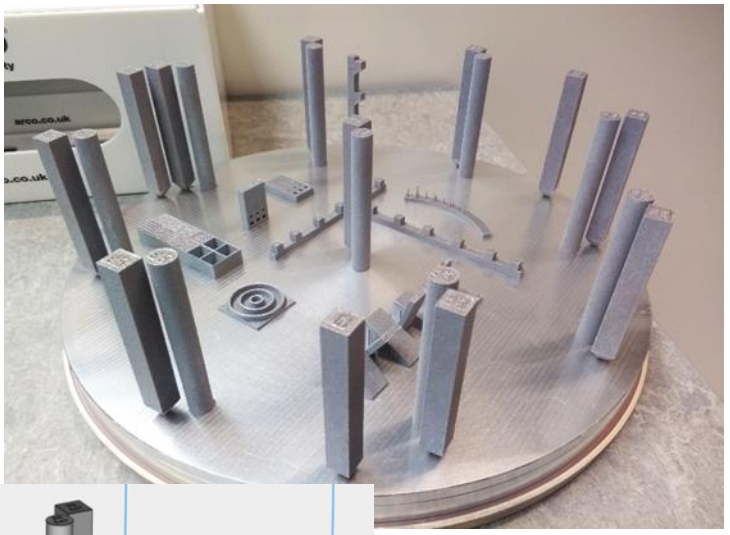
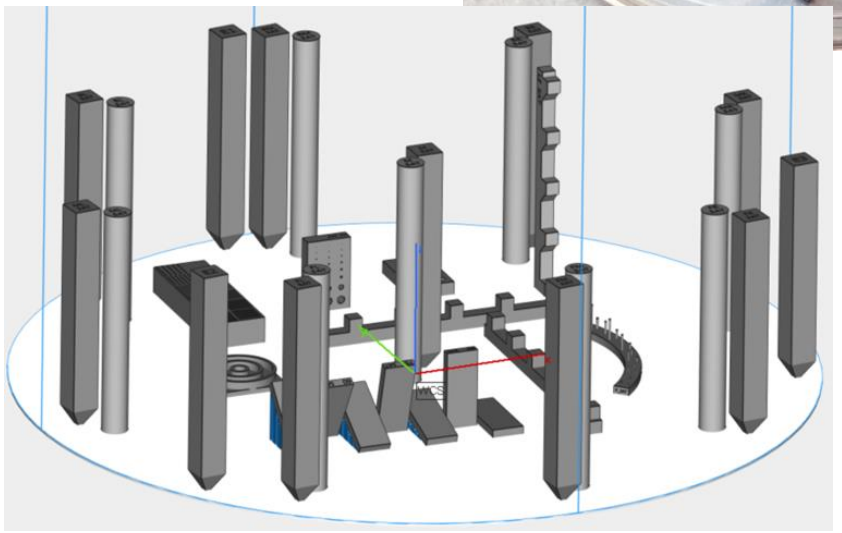
Not Just About Documentation

You may need to retain samples:

- Witness samples
- Powder samples





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Witness samples

Some of the things which can go wrong

- Not built !
- Not built at the same time as the parts !
- Not the correct location, orientation or parameters !
- Not labelled properly !
- Losing them (or disposing of them)

Build preparation sheets significantly reduces the risk

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Question ?

1.What is the aim of the witness samples ?

2. What are the limitations ?

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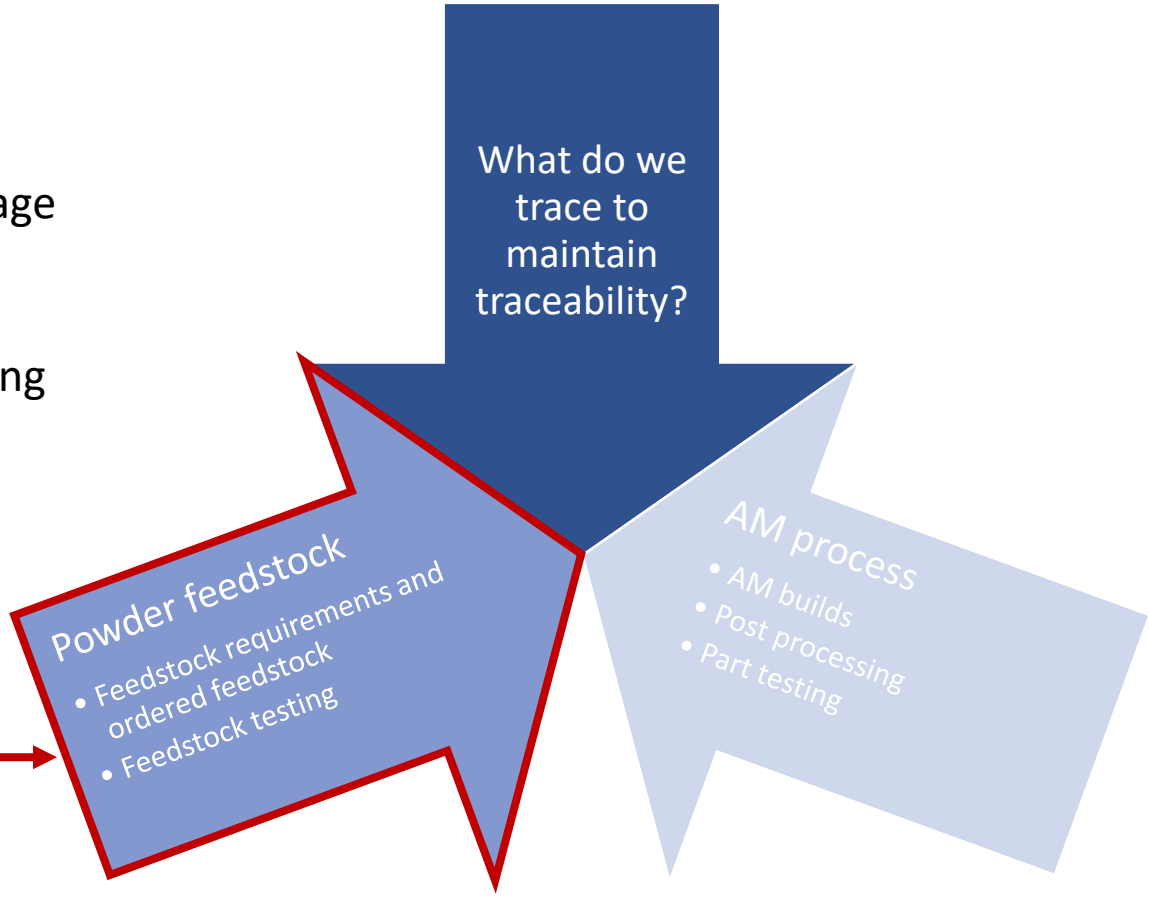
Chain Traceability in Additive Manufacturing

- Feedstock procurement
- Feedstock receipt and storage
- Feedstock testing

- Production & post processing

We will focus on powder feedstock to show the depth of information



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Feedstock procurement

Co-funded by the Erasmus+ Programme of the European Union

- Feedstock requirements need to be retained (a proposal, copies of emails, excel spreadsheet)

Procurement e-form and **purchase order** are evidence of the conformity of the ordered feedstock to specified requirements

Information captured:

- Supplier details
- Product description
- Material type
- Alloy name
- Alloy specification
- Quantity
- Nominal particle size
- Customer purchase order

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Feedstock receipt & storage

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Certificate of Conformity (CoC)

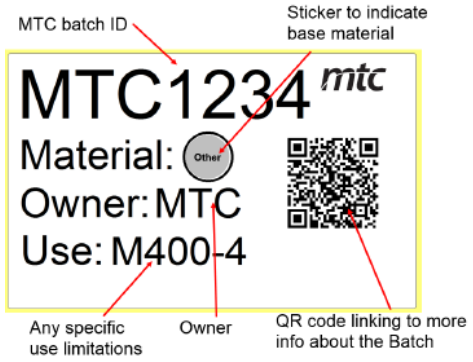
Information captured:

- Supplier
- Customer Purchase Order
- Alloy name
- Supplier batch number
- Dispatch number
- Weight
- Nominal particle size
- Alloy specification
- Number of certificate of analysis

Powder tracker is a log of all powder batches in stock

Information captured:

- MTC batch ID
- Supplier batch number
- Date receipted
- Manufacturer
- Initial weight and a number of containers
- Current weight and a number of containers
- Location
- Material type, alloy name, nominal particle size
- AM process, AM machine
- Feedstock status (active, retired, top-up, quarantined, exhausted, not in use, contaminated)



	Base Material
Al	Aluminium
Fe	Iron/Steel
Ni	Nickel
Ti	Titanium
CONF	CONFIDENTIAL
Other	Other

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Feedstock testing

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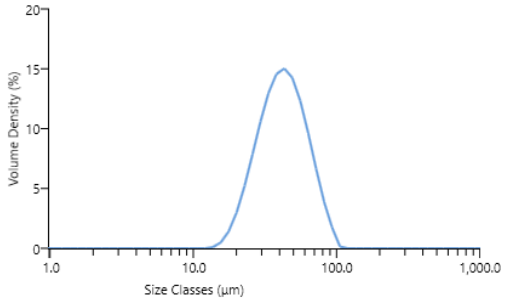
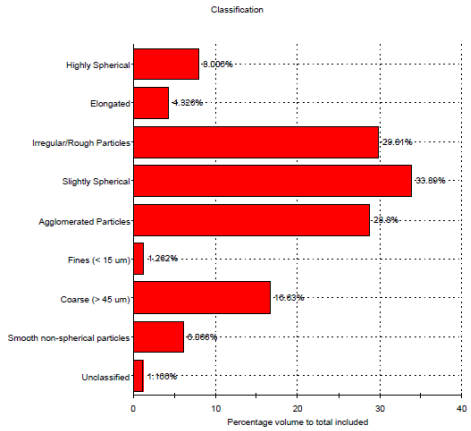
Sample testing log

- The log of all powder samples tested

  Information captured:

  - Materials Lab Sample ID
  - MTC batch ID/supplier batch number
  - Sample description (e.g. project name, project code, build ID)
  - Material
  - Alloy name
  - Weight
  - Date
  - Additional information





- All samples and material test data are labelled in a standardised way and can be identified using the Materials Lab Sample ID

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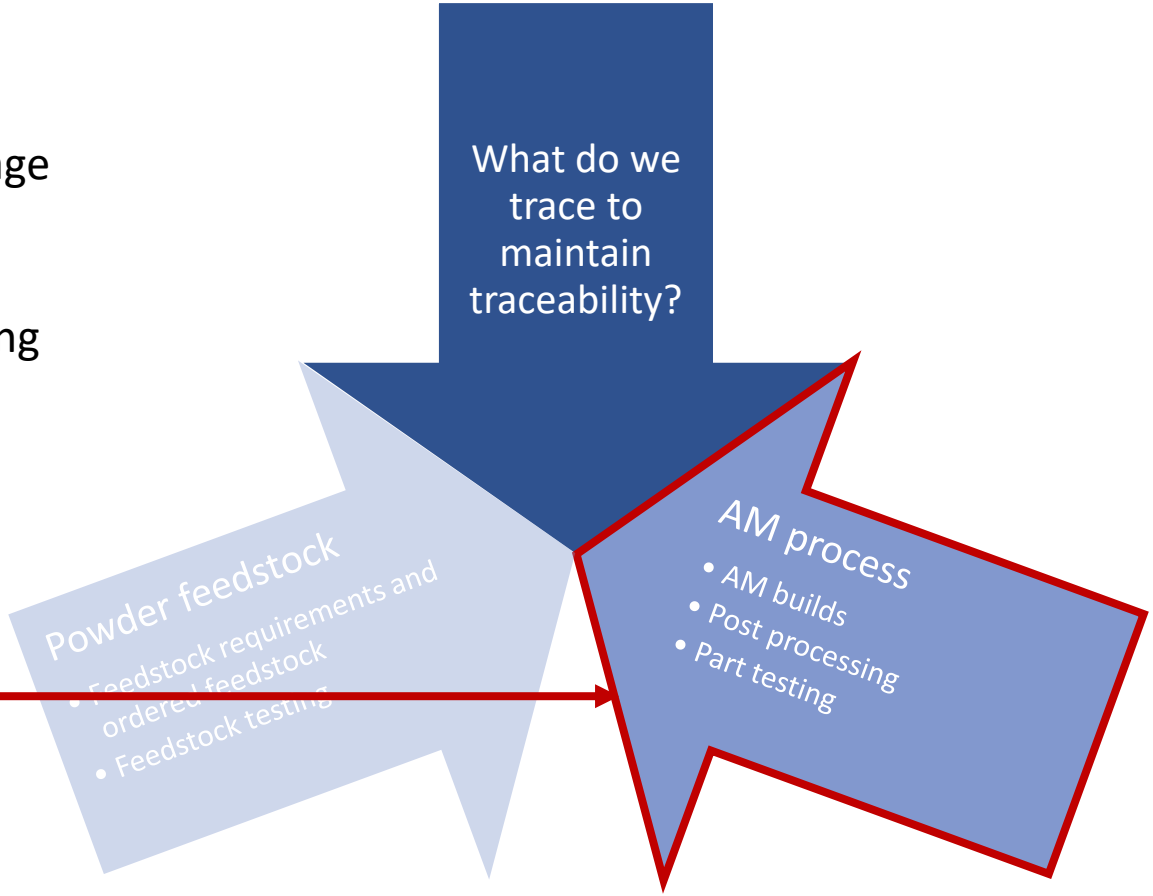
Chain Traceability in Additive Manufacturing

- Feedstock procurement
- Feedstock receipt and storage
- Feedstock testing

- Production & post processing

We will focus on AM process to show the depth of information



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EXAMPLE from MTC

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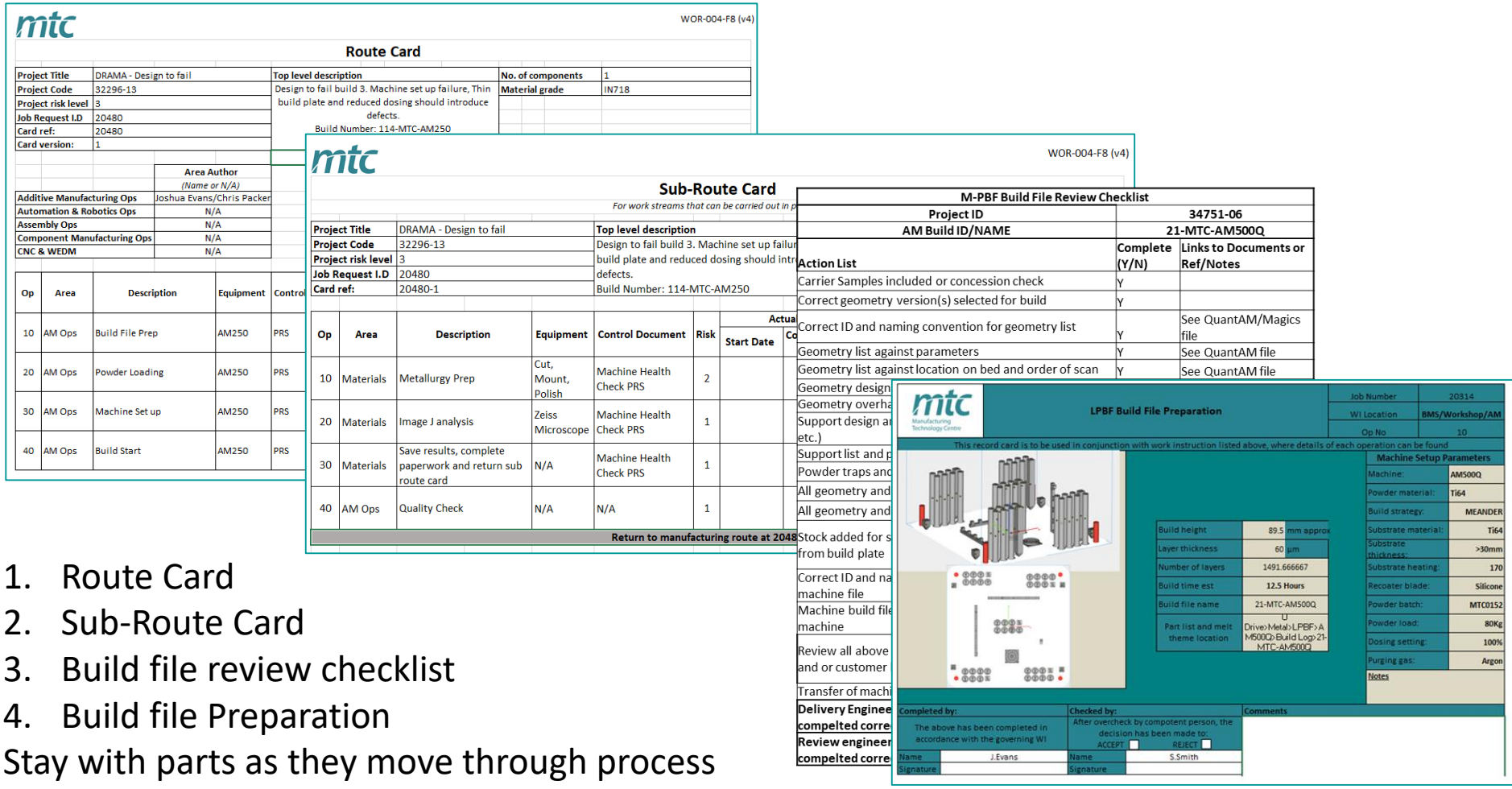
AM Production Pack



Route Card — WOR-004-F8 (v4)

Project Title	DRAMA - Design to fail	Top level description	No. of components: 1
Project Code	32296-13	Design to fail build 3. Machine set up failure, Thin build plate and reduced dosing should introduce defects. Build Number: 114-MTC-AM250	Material grade: IN718
Project risk level	3		
Job Request I.D	20480		
Card ref:	20480		
Card version:	1		

	Area Author (Name or N/A)
Additive Manufacturing Ops	Joshua Evans/Chris Packer
Automation & Robotics Ops	N/A
Assembly Ops	N/A
Component Manufacturing Ops	N/A
CNC & WEDM	N/A

Op	Area	Description	Equipment	Control
10	AM Ops	Build File Prep	AM250	PRS
20	AM Ops	Powder Loading	AM250	PRS
30	AM Ops	Machine Set up	AM250	PRS
40	AM Ops	Build Start	AM250	PRS

Sub-Route Card — WOR-004-F8 (v4)

For work streams that can be carried out in p

Project Title	DRAMA - Design to fail	Top level description	Design to fail build 3. Machine set up failur
Project Code	32296-13		build plate and reduced dosing should intr
Project risk level	3		defects.
Job Request I.D	20480		Build Number: 114-MTC-AM250
Card ref:	20480-1		

Op	Area	Description	Equipment	Control Document	Risk	Actua Start Date	Co
10	Materials	Metallurgy Prep	Cut, Mount, Polish	Machine Health Check PRS	2		
20	Materials	Image J analysis	Zeiss Microscope	Machine Health Check PRS	1		
30	Materials	Save results, complete paperwork and return sub route card	N/A	Machine Health Check PRS	1		
40	AM Ops	Quality Check	N/A	N/A	1		
Return to manufacturing route at 2048							

M-PBF Build File Review Checklist

Project ID	34751-06
AM Build ID/NAME	21-MTC-AM500Q

Action List	Complete (Y/N)	Links to Documents or Ref/Notes
Carrier Samples included or concession check	Y	
Correct geometry version(s) selected for build	Y	
Correct ID and naming convention for geometry list	Y	See QuantAM/Magics file
Geometry list against parameters	Y	See QuantAM file
Geometry list against location on bed and order of scan	Y	See QuantAM file
Geometry design		
Geometry overha		
Support design a etc.)		
Support list and p		
Powder traps and		
All geometry and		
All geometry and		
Stock added for s from build plate		
Correct ID and na machine file		
Machine build file machine		
Review all above and or customer		
Transfer of machi		
Delivery Enginee compelted corre		
Review engineer compelted corre		

LPBF Build File Preparation

Job Number: 20314 | WI Location: BMS/Workshop/AM | Op No: 10

This record card is to be used in conjunction with work instruction listed above, where details of each operation can be found

Build height	89.5 mm approx
Layer thickness	60 µm
Number of layers	1491.666667
Build time est	12.5 Hours
Build file name	21-MTC-AM500Q
Part list and melt theme location	U Drive>Metal>LPBF>AM500Q>Build Log>21-MTC-AM500Q

Machine Setup Parameters	
Machine:	AM500Q
Powder material:	Ti64
Build strategy:	MEANDER
Substrate material:	Ti64
Substrate thickness:	>30mm
Substrate heating:	170
Recoater blade:	Silicone
Powder batch:	MTC0152
Powder load:	80Kg
Dosing setting:	100%
Purging gas:	Argon
Notes	

Completed by:	Checked by:	Comments
The above has been completed in accordance with the governing WI	After overcheck by competent person, the decision has been made to: ACCEPT ☐ REJECT ☐	
Name: J.Evans	Name: S.Smith	
Signature:	Signature:	

1. Route Card
2. Sub-Route Card
3. Build file review checklist
4. Build file Preparation

Stay with parts as they move through process

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1.Route Card

- **Manufacture operation workflow**
- **Operation workflow control gates**

mtc

WOR-004-F8 (v4)

Route Card

Project Title	DRAMA - Design to fail	**Top level description**		**No. of components**	1
Project Code	32296-13	Design to fail build 3. Machine set up failure, Thin build plate and reduced dosing should introduce defects. Build Number: 114-MTC-AM250		**Material grade**	IN718
Project risk level	3				
Job Request I.D	20480				
Card ref:	20480				
Card version:	1				

	Area Author *(Name or N/A)*		**Area Author** *(Name or N/A)*
Additive Manufacturing Ops	Joshua Evans/Chris Packer	**Maintenance**	N/A
Automation & Robotics Ops	N/A	**Materials Labs**	N/A
Assembly Ops	N/A	**Metrology Lab**	N/A
Component Manufacturing Ops	N/A	**Customer**	Llyr Jones
CNC & WEDM	N/A		

Op	**Area**	**Description**	**Equipment**	**Control Document**	**Risk**	**Actual**		**Outcome** *(tick one)*		**Completion Stamp**	**Notes / Progress Stamps / Overcheck Stamps**
						Start Date	**Completion Date**	**C**	**H**		
10	AM Ops	Build File Prep	AM250	PRS	3						
20	AM Ops	Powder Loading	AM250	PRS	2						
30	AM Ops	Machine Set up	AM250	PRS	3						
40	AM Ops	Build Start	AM250	PRS	2						

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2.Sub-Route Card

- **Material and part flow/planning through manufacture**

mtc

WOR-004-F8 (v4)

Sub-Route Card

For work streams that can be carried out in parallel

Project Title	DRAMA - Design to fail	**Top level description**		**No. of components**	4
Project Code	32296-13	Design to fail build 3. Machine set up failure, Thin build plate and reduced dosing should introduce defects. Build Number: 114-MTC-AM250		**Material grade**	IN718
Project risk level	3			**List component IDs**	
Job Request I.D	20480			HC1, HC2, HC3, HC4	
Card ref:	20480-1				

Op	Area	Description	Equipment	Control Document	Risk	Actual		Outcom (tick one)		Completion Stamp	Notes / Progress Stamps / Overcheck Stamps
						Start Date	Completion Date	C	H		
10	Materials	Metallurgy Prep	Cut, Mount, Polish	Machine Health Check PRS	2						
20	Materials	Image J analysis	Zeiss Microscope	Machine Health Check PRS	1						
30	Materials	Save results, complete paperwork and return sub route card	N/A	Machine Health Check PRS	1						
40	AM Ops	Quality Check	N/A	N/A	1						
Return to manufacturing route at 20480 110											

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3.Build File Review Checklist

- Key operation step information and data capture
- Operation peer review and approval

M-PBF Build File Review Checklist		
Project ID	**34751-06**	
AM Build ID/NAME	**21-MTC-AM500Q**	
Action List	**Complete (Y/N)**	**Links to Documents or Ref/Notes**
Carrier Samples included or concession check	Y	
Correct geometry version(s) selected for build	Y	
Correct ID and naming convention for geometry list	Y	See QuantAM/Magics file
Geometry list against parameters	Y	See QuantAM file
Geometry list against location on bed and order of scan	Y	See QuantAM file
Geometry design and build-ability	Y	
Geometry overhang check	Y	
Support design and connection to geometry (teeth design etc.)	N/A	
Support list and parameters	N/A	
Powder traps and powder removal possible	N/A	
All geometry and support within build envelope	Y	
All geometry and supports connected to build plate	Y	
Stock added for support or sacraficial material removal from build plate	Y	See control plan (AM CRP Project Workshop Requirement Spec)
Correct ID and naming convention for build model and machine file	Y	
Machine build file settings correct on build file and machine	Y	
Review all above against AM build requirements capture and or customer build specification	Y	Stress relief cycle defined by standard SAT/FAT
Transfer of machine build file to machine	Y	JE to complete
Delivery Engineer Signiture that all above has been compelted correctly	J Evans - 05/11/2020	
Review engineer Signiture that all above has been compelted correctly	S Smith - 05/11/2020	

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4.Build File Preparation Sheet

Shows all of the parts to be built, their **location**, **orientation** and **labelling**

+

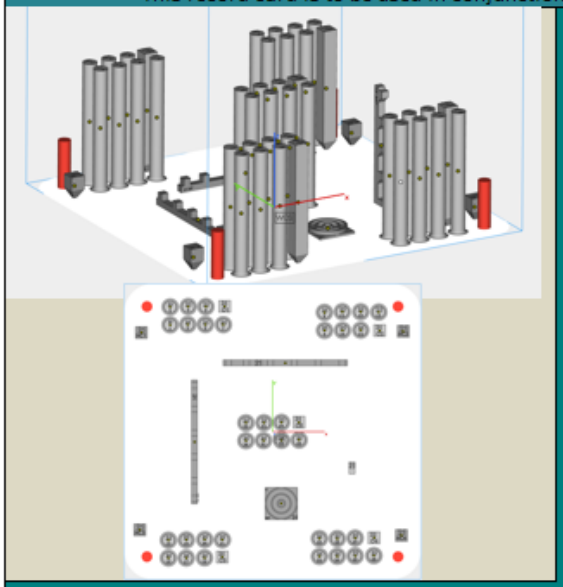
M/C set up parameters

mtc Manufacturing Technology Centre

LPBF Build File Preparation

Job Number	20314
WI Location	BMS/Workshop/AM
Op No	10

This record card is to be used in conjunction with work instruction listed above, where details of each operation can be found



Build height	89.5 mm approx
Layer thickness	60 µm
Number of layers	1491.666667
Build time est	**12.5 Hours**
Build file name	21-MTC-AM500Q
Part list and melt theme location	U Drive>Metal>LPBF>AM500Q>Build Log>21-MTC-AM500Q

Machine Setup Parameters

Machine:	AM500Q
Powder material:	Ti64
Build strategy:	MEANDER
Substrate material:	Ti64
Substrate thickness:	>30mm
Substrate heating:	170
Recoater blade:	Silicone
Powder batch:	MTC0152
Powder load:	80Kg
Dosing setting:	100%
Purging gas:	Argon

Notes

Completed by:		Checked by:		Comments
The above has been completed in accordance with the governing WI		After overcheck by compotent person, the decision has been made to: ACCEPT ☐ REJECT ☐		
Name	J.Evans	Name	S.Smith	
Signature		Signature		

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Traceability for AM: In-Process Monitoring Available for AM

AM Process	Machine Manufacturer	'Module' name	Failure Mode Monitored	Parameter Altered	Equipment
Electron Beam Powder Bed Fusion	Arcam	LayerQam™	Porosity	N/A	Camera
Laser Powder Bed Fusion	B6 Sigma, Inc. (specialist)	PrintRite3D® INSPECT™	Unknown	N/A	Thermocouple and high speed camera
Laser Powder Bed Fusion	Concept Laser	QM melt pool	Melt pool monitoring	Laser Power	High-speed CMOS-camera
Laser Powder Bed Fusion	EOS	N/A	Unknown	N/A	Camera
Direct Energy Deposition	DEMCON	LCC 100	Melt pool monitoring	Laser Power	Camera
Direct Energy Deposition	DM3D Technology	DMD closed-loop feedback system	Melt pool monitoring and build height	Laser Power	Dual-colour pyrometer and three high-speed CCD cameras
Direct Energy Deposition	Laser Depth	LD-600	Depth measurement	Laser Power	Inline coherent imaging
Direct Energy Deposition	Promotec	PD 2000	Melt pool monitoring	N/A	CMOS-camera
Direct Energy Deposition	Promotec	PM 7000	Melt pool monitoring	N/A	1D photo detector
Direct Energy Deposition	Stratonics	ThermaViz system	Melt pool temperature	Laser Power	Two-wavelength imaging pyrometer

Source: KHUB-AM-0010-Correlation of IPM Data to XCT Inspection -v1.0

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Traceability for AM: In-Process Monitoring Available for AM

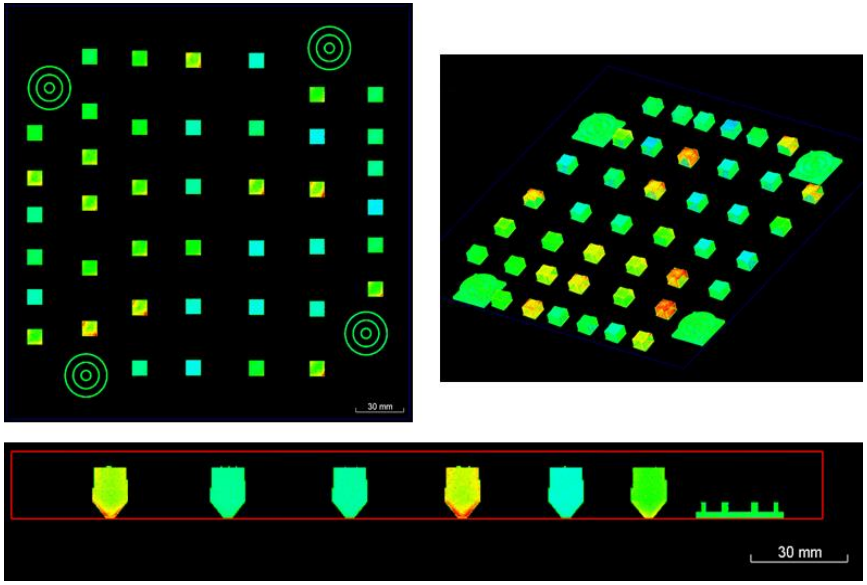

Figure. IPM data representation in the Renishaw InfiniAM Spectral software generated by MTC.

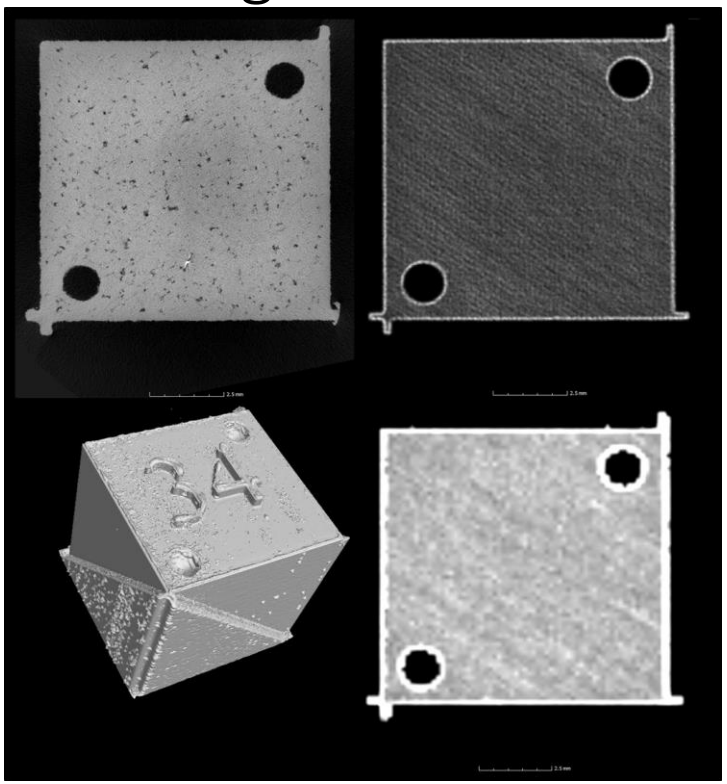

Figure. IPM data representation for single layer against XCT image for the same sample and layer

Source: KHUB-AM-0010-Correlation of IPM Data to XCT Inspection -v1.0

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5 min - Video

- https://www.youtube.com/watch?v=tyJ4i8Jt70Y

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Traceability

- Needs to be planned, managed and regularly checked (tested) and improved…do not take this lightly and do not wait until a customer calls..

Things which can and often do go wrong;

- Not capturing the right data
- Not capturing enough data
- Lost, corrupt, confusing or poorly labelled data
- False reliance on suppliers

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Finally….

Traceability is a PAIN but it is essential

As you will remember from the Sioux City crash when something goes wrong everyone is trying to“blame” someone else

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Summary of Day 3 – Part 1

- We have discussed how QMS provides the framework and traceability foundation for CQS

- After the break we will we will look at some examples of how it affects the way the way a business operates..

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Mentimeter – Practice question

Practice questions: Day3-Q1

PQ1 –Traceability

Q- What should traceability cover?

Select one answer which applies

1 Only covers in-house manufacturing operations.
2 Only covers supply of goods/services from outside of the business.
3 Covers internal and external activities.

(A- point 3 is correct)

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Short break …10 mins

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DAY 3
PART 2

3

10.00 TRAINING

~45 MINS

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Additive Manufacturing Process Specification (AMPS)

- AMPS defines the entire end-to-end process which must be followed to ensure that a part meets the required quality – and the process followed complies with prevailing CQS requirements.

AMPS gets into the detail of the process

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AM Process Specification

Some examples

- NASA 3717 for metallurgical control
- NASA 3716 for manufacture of spaceflight hardware
- ASTM F3303 Standard for Additive Manufacturing
- AMS 7003 Laser Powder Bed Process

You have been supplied with copies of NASA 3717 and 3716

MEASUREMENT SYSTEM IDENTIFICATION METRIC/SI (ENGLISH) UNITS

National Aeronautics and Space Administration

MSFC-SPEC-3717
BASELINE
EFFECTIVE DATE: October 18, 2017

George C. Marshall Space Flight Center
Marshall Space Flight Center, Alabama 35812

EM20

MSFC TECHNICAL STANDARD

SPECIFICATION FOR CONTROL AND QUALIFICATION OF LASER POWDER BED FUSION METALLURGICAL PROCESSES

Approved for Public Release; Distribution is Unlimited

CHECK THE MASTER LIST — VERIFY THAT THIS IS THE CORRECT VERSION BEFORE USE

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AMPS Encompasses

1. Facility specification
2. EH&S specification
3. People and skills specification
4. Equipment
5. Design data
6. Material/feedstock specification
7. Specification of other consumables
8. Operation specification;
9. KPVs and Process Window Control
10. Inspection specification

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Facility specification

Includes…..

- layout plan
- People, material workflow and segregation
- Climate control for temperature and humidity

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EH&S (Environment health & safety)

Includes…..

- PPE (personal protective equipment)
- Barriers/partitions
- Closed rooms
- Local exhaust ventilation
- Risk assessments and safe working practice
- Material COSHH…

https://www.bsigroup.com

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People and skills specification;

Includes….

- List of approved users
- Roles and responsibilities
- Skills and training matrix

This is a hot topic
for many end-users

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Equipment

Includes….

- Performance validation(Factory acceptance Tests - FATS)
- Installation, commissioning (Site acceptance Tests - SATS)
- Servicing, maintenance calibration for AM machine and other equipment used in the process

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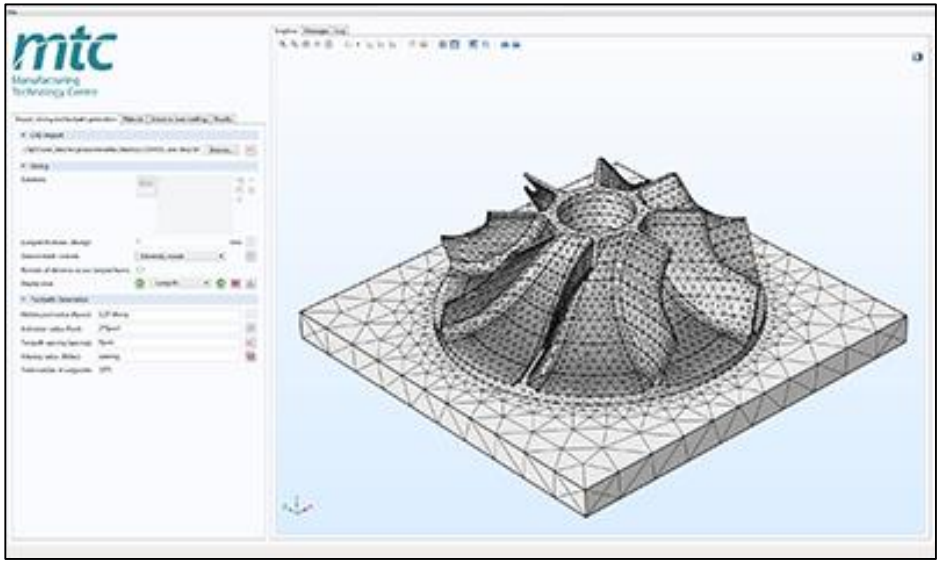
Design data

Includes..

- ID registers
- Version control
- Validation of fidelity



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Material/feedstock specification

For example, for metal powder this includes;

- Definition of alloy,
- Particle form/shape, size range, size distribution
- Chemical weighting
- Interstitial contamination

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Specification of other consumables

Including…..

- Compressed air type
- Inert gas type
- Filter grade
- Alcohol cleaning grade
- Build plate specification and drawings

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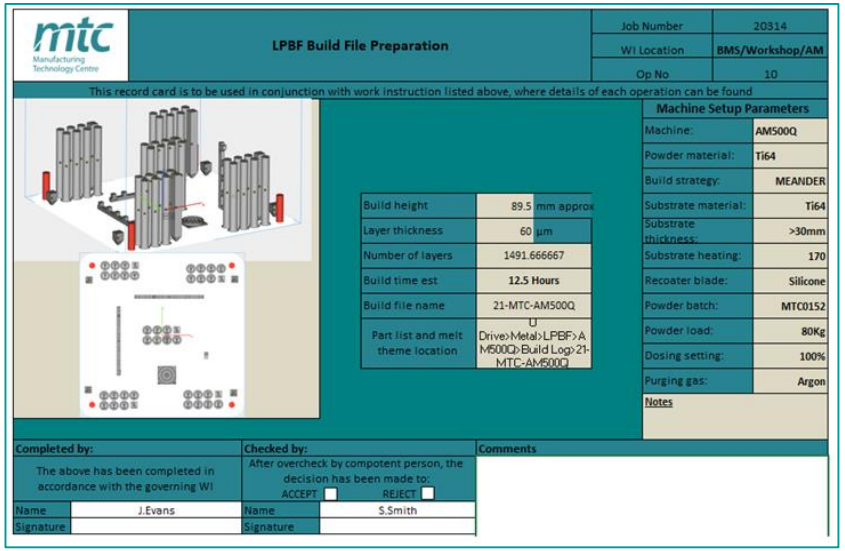
Operation specification

Includes

- Work instructions, Guidelines, check sheets, route cards, manufacturing packs with control plans/process record sheets + process parameters



mtc Manufacturing Technology Centre

LPBF Build File Preparation

Job Number	20314
WI Location	BMS/Workshop/AM
Op No	10

This record card is to be used in conjunction with work instruction listed above, where details of each operation can be found

Build height	89.5 mm approx
Layer thickness	60 µm
Number of layers	1491.666667
Build time est	12.5 Hours
Build file name	21-MTC-AM500Q
Part list and melt theme location	U Drive>Metal>LPBF>AM500Q>Build Log>21-MTC-AM500Q

Machine Setup Parameters

Machine:	AM500Q
Powder material:	Ti64
Build strategy:	MEANDER
Substrate material:	Ti64
Substrate thickness:	>30mm
Substrate heating:	170
Recoater blade:	Silicone
Powder batch:	MTC0152
Powder load:	80Kg
Dosing setting:	100%
Purging gas:	Argon

Notes

Completed by:		Checked by:		Comments
The above has been completed in accordance with the governing WI		After overcheck by compotent person, the decision has been made to: ACCEPT ☐ REJECT ☐		
Name	J.Evans	Name	S.Smith	
Signature		Signature		

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KPVs (Key Process Variables) & Process Window Control

Includes;
process variable measurement against necessary output criteria and fix setting/range by control plan

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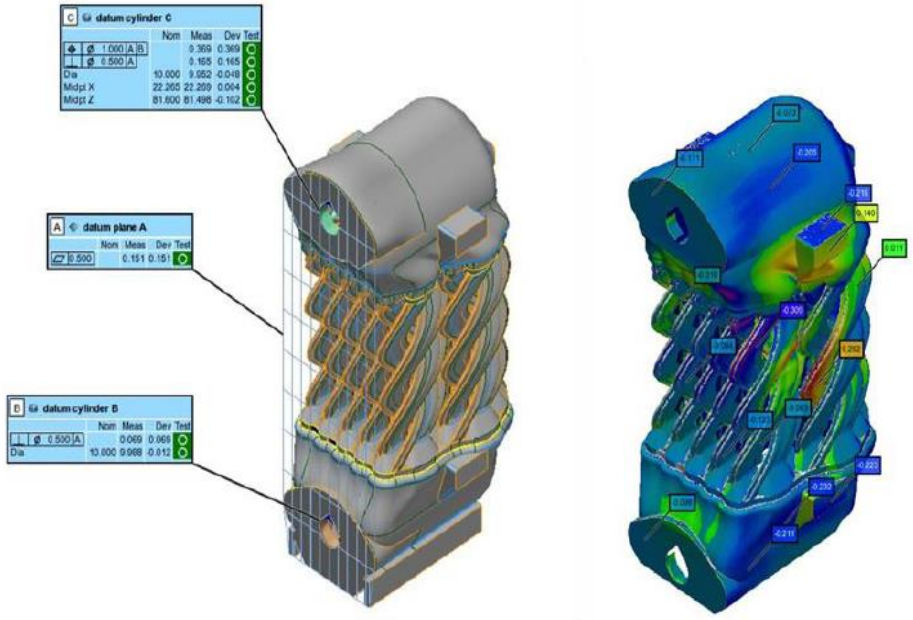
Inspection specification

- Part drawings and detailed inspection plans



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Further information is provided in this report which has been sent to you

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Example from the Aerospace Sector

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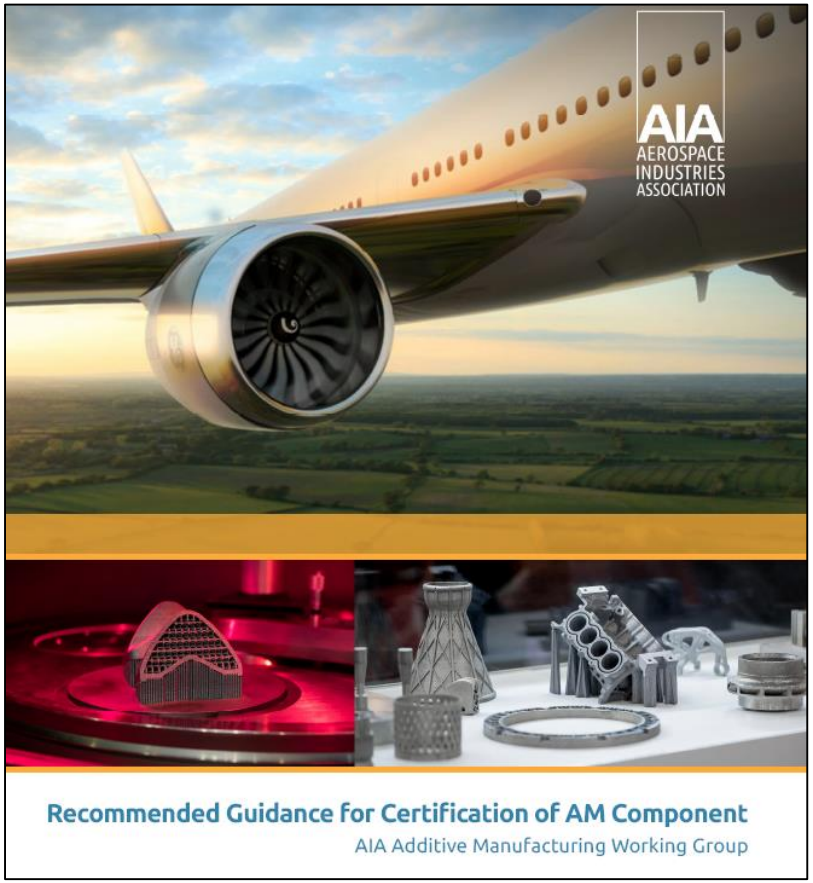
Recommended Guidance for Certification of AM Components
AIA Additive Manufacturing Working Group

You have been provided with a copy of this report



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Process Control Documents

Infrastructure
- Facility Control Plan
- Operator Training and Qualification Plan
- Work Instruction Plan
- Software Configuration Control Plan

Machine Qualification Plans
- Key Process Variable (KPV) Plan
- Machine Configuration Plan
- Preventative Maintenance Plan
- Machine Calibration Plan
- Machine Requalification Plan

Feedstock Control Plan
- Feedstock Lot Control Plan
- Feedstock Handling Plan
- Powder Feedstock Re-use Plan
- Machine and Material Alloy Change
- Contamination Avoidance Plan

Part Production Plans
- Engineering Requirements Plan
- Manufacturing Part Definition Plan
- Machine Parameters Plan
- Build Interruption Plan
- Quality Control Plan
- In-Process Monitoring Inspection Plan
- Record Keeping Plan

Post-Process Plans
- Powder Removal Plan
- Stress Relief Plan
- Hot Isostatic Press (HIP) Plan
- Heat Treatment Plan
- Build Plate Removal Plan
- Support Removal Plan
- Surface Enhancement Plan

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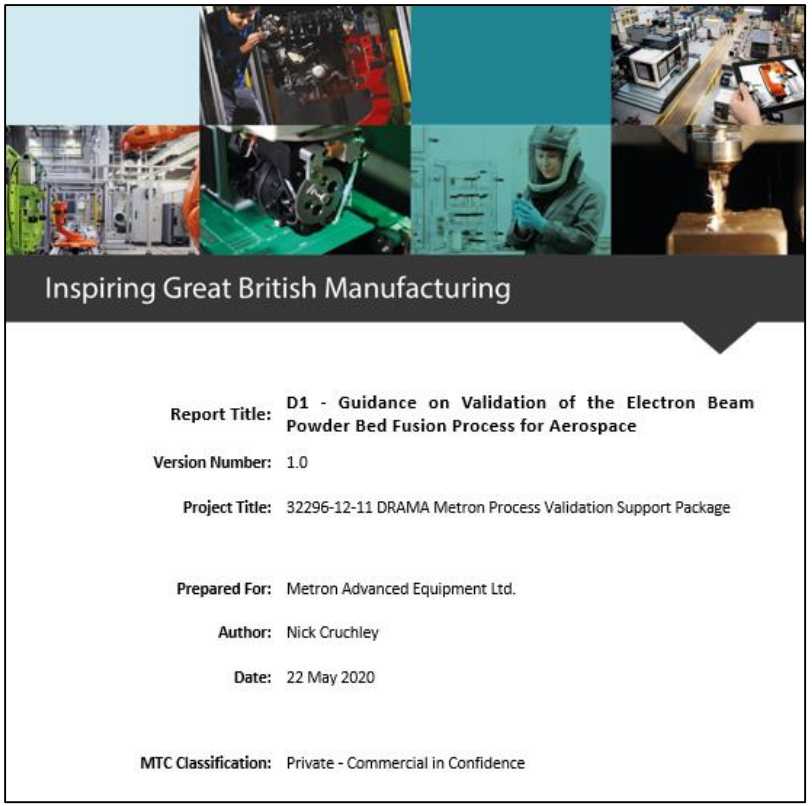
Metron case study

you have been provided with a copy of this report

some of the information is contained in the following slides



Inspiring Great British Manufacturing

Report Title:	**D1 - Guidance on Validation of the Electron Beam Powder Bed Fusion Process for Aerospace**
Version Number:	1.0
Project Title:	32296-12-11 DRAMA Metron Process Validation Support Package
Prepared For:	Metron Advanced Equipment Ltd.
Author:	Nick Cruchley
Date:	22 May 2020
MTC Classification:	Private - Commercial in Confidence

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Definitions of terminology used in within the context of production of components for the aerospace industry

Term	Quoted Definition	Definition Source	Reference
Certification	"A procedure by which a third party gives written assurance that a product, process or service conforms to a specified requirement."	MAASAG Paper 124 Issue 1	(Lunt, et al., 2018)
Qualification	"The demonstration that the product, process or service conforms to a specified requirement."	MAASAG Paper 124 Issue 1	(Lunt, et al., 2018)
Validation	"Activities performed to demonstrate that a product is capable of meeting the requirements for the specified application or intended use." Note: Validation can also apply to a manufacturing process.	SABRe Supplier Management System Requirements Definition	(Rolls-Royce, 2019)
Verification	"Verification uses objective evidence to confirm that specified requirements have been met."	SABRe Supplier Management System Requirements Definition	(Rolls-Royce, 2019)

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Airworthiness Regulations

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- **CAA/ EASA:** the regulatory bodies which oversee the safety of the aerospace sector
- **Design Organisation:** "responsible for the design of products, parts and appliances or for changes or repairs" …… for example Airbus, Rolls-Royce.
- **Production Organisation:** "responsible for the manufacture of products, parts and appliances" … must demonstrate appropriate capability.. have agreement in place with Design Organisation; demonstrate a robust Quality System; and have a nominated independent owner of quality management.
- Obtaining these approvals **can take years**….includes visits from National Aviation Authority (the CAA for the UK)

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Subcontracting

- Design Organisation or Production Organisation can subcontract to another company but legal responsibility for the airworthiness of the products remains with them (ie you can not subcontract the responsibility)

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Working to standards

- AS9100D - aerospace industry standard for quality management systems.
- Special processes (such as heat treatment) are audited by an organisation called **NADCAP** (National Aerospace and Defense Contractors Accreditation Program).
- Aerospace organisations still impose their own specific requirements.

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Manufacturing Process Approval

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- Even if baseline accreditations/ approvals are in place, supplier has to prove **production readiness for each new product introduced**…for example manufacturing readiness level (MRL) used by Rolls-Royce.
- Requirements for process approval may be different for each component, depending on e.g. their processing route or criticality.
- Design Organisation provides detailed material and process specifications….may even specify the feed-stock supplier.
- Qualification process has to be undertaken for **each product** supplied to each aircraft type.
- Design Organisation may permit learning to be 'read across' from one product to another or from one process to another.
- For AM we still don't have a good understanding of what we can read across.

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Colin should have used on Day 1

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Table 2: Reviewed documents referencing to specific EB-PBF process tasks

	Reviewed Documents										
	NADCAP Audit Criteria For Laser and Electron Beam Metallic Powder Bed Additive Manufacturing	MASAAG Paper 124 Guidance Note On the Qualification and Certification of Additive Manufactured Parts for Military Aviation	AIA - Recommended Guidance for Certification of AM components	FAA Job Aid for Evaluating Additive Manufacturing Facilities and Processes	NASA MSFC-STD-3717 Specification For Control and Qualification of Laser Powder Bed Fusion Metallurgical Processes	ASTM F2924 Standard Specification for Additive Manufacturing Titanium-6 Aluminium-4 Vanadium with Powder Bed Fusion	ASTM F3049 Standard Guide for Characterizing Properties of Metal Powders Used for Additive Manufacturing Processes	ASTM F3301 Standard for Additive Manufacturing – Post Processing Methods – Standard Specification for Thermal Post-Processing Metal Parts Made Via Powder Bed Fusion	ASTM F3303 Standard for Additive Manufacturing – Process Characteristics and Performance: Practice for Metal Powder Bed Fusion Process to Meet Critical Applications	AMS 2801B Heat Treatment of Titanium Alloy Parts	AMS7003 Laser Powder Bed Fusion Process
Powder specification	X		X		X	X			X		
Powder Receipt	X			X							
Powder handling	X	X		X	X						
Powder Storage	X	X		X	X				X		X
Powder blending		X			X	X					X
Powder recycling		X			X	X			X		
Powder testing						X	X				
Key process variables		X	X								X
Machine operation	X	X	X						X		
Build Monitoring		X		X							
Build pauses	X	X			X						X
Machine maintenance	X	X		X	X				X		X
Support removal	X		X								
Thermal post processing	X	X	X		X	X		X		X	
Surface Finishing		X									
Machining											
Inspection	X	X	X	X							

Checklist is in course handbook

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Feed-stock control

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4.1 Powder

4.1.1 Specification

The sources reviewed containing information on the specification of powder being procured and for continual testing is displayed in Table 2. Based on the information reviewed the MTC suggests that Metron's processes must include the following:

- Powder suppliers are to hold AS9100 or an equivalent accreditation
- A clear powder specification is used when procuring powder feedstock including acceptable limits, methods of sampling, methods of testing and acceptable testing tolerances on the following metrics:
  - Chemistry
  - Particle size distribution (PSD)
  - Powder morphology (at least qualitative requirements)
  - Flowability
  - Contamination requirements
- In addition to this the powder specification should:
  - Explicitly state the powder manufacturing method (incl. atomising gas)
  - Place controls on the blending of powder heats into powder lots (i.e. requiring each blended heat to meet the feedstock specification)
  - State the requirements for feedstock packaging (incl. environmental controls) that by design explicitly prevent moisture from entering.

Note: Multiple standards (ASTM F3303) explicitly prohibit the placing of desiccants or other materials in contact with the feedstock materials.

- A certificate of conformance (CoC) to the supplied specification
  - Identifiers of powder heat and blended lot with date and location of production allowing traceability back to the specific heat.
- Powder should be verified against this specification prior to use

4.1.7 Testing

The sources reviewed provided little guidance on the procedures and methods for powder testing, however, ASTM F3049-14 can provide some guidance on this. Together with this standard the MTC recommends following the test standards for verifying the powder feedstock metrics displayed in the table below.

Table 3: Test standards governing the relevant metallic powder test methods employed for the suggested material purchasing specification

Property	Test	Governing standard
Powder sampling	Sampling method	ASTM B215
Particle size determination*	Sieve analysis	ASTM B214
	Light scattering method	ASTM B822
Morphology	Morphology definitions only**	ASTM B243
Chemical composition	Inert gas fusion	ASTM E1447
	Combustion Analysis	ASTM E1941
	Inductively Coupled Plasma Atomic Emission Spectrometry	ASTM E2371
	Wavelength Dispersive X-ray fluorescence	ASTM E539
Flowability	Hall flow	ASTM B213 & B855
	Carney flow	ASTM B964
Contamination	N/a	No current governing standard or commonly accepted test method
Density	Hall flow	ASTM B212
	Carney flow	ASTM B417
	Scott volumeter	ASTM B329
	Arnold meter	ASTM B703
	Tap Density	ASTM B527
	Skeletal density	ASTM B923

* Non standardised light scattering methods may be applicable

** Only defines definitions of powder shapes – no standard for qualification of powder morphology currently exists

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Machine operation

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4.2.2 Machine operation

The sources reviewed containing information on procedures for machine set up is displayed in Table 2. Based on the information reviewed the MTC suggests the following advice.

Note: It is strongly suggested by multiple standards and the MTC that a machine is allocated to a single material as the changing over of materials in the context of validation or qualification for aerospace is too high risk and runs a large amount of machine requalification effort.

All operators shall be suitably trained or qualified to operate the equipment and a documented record of operator for each stage of the manufacturing process should be kept. The operator may be considered a KPV and if so should be controlled accordingly.

The equipment/machinery to be used during manufacture (including pre and post processing) should be defined and documented at a minimum to the following level:

- Machine, make and model
- Serial number
- Date of machine configuration
- Software and hardware version numbers
- Recoater configuration, material and condition
- Recoater speed
- Build platform material and configuration
- Preheating temperature
- Powder dosing range
- Gas composition/grade
- Vacuum quality
- Oxygen limits
- Temperature limits
- Dew point and moisture control

Documented procedures should be in place to ensure that the quality of the all build plates are controlled, this includes:

- Build plate cleanliness and condition
- Build plate is free from contamination and defects
- Traceability between manufactured component and build plate
- Tolerances and material requirements of the build plate including: flatness, finish, thickness, and alloy
- Visual inspection of build plates is carried out and that non-conforming build plates are disregarded

Similar process control could be consider for other key consumables such as recoaters and process gases.

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Some customers can be very demanding

recently we were asked to complete an **800 line** checklist for <u>every</u> part made

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Question ?

Is it worth the trouble of providing all of this information

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Often said that the paperwork covering the design, certification and manufacture of an aircraft weights more than the aircraft itself !

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Although we have covered an example from the aerospace sector the list of manufacturing aspects which must be controlled are consistent across all sectors

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Summary Day 3 – Part 2

We have covered an overview of the issues which must be considered and controlled

We have looked at how the aerospace sectors specifies the critical issues which must be managed

After the break we will look at product verification and inspection

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Short break …5 mins

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DAY 3
PART 3

3

10.50 TRAINING

20 MINS

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Question ?

What happens if you design a part which can't be inspected properly ?

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"If you can't inspect it then you can't fly it" (Airbus)

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Product Verification & Inspection

Need to plan the inspection process from the outset

- Design for inspection
- Assess limits of detection of the inspection processes
- Devise, test and implement Inspection procedure

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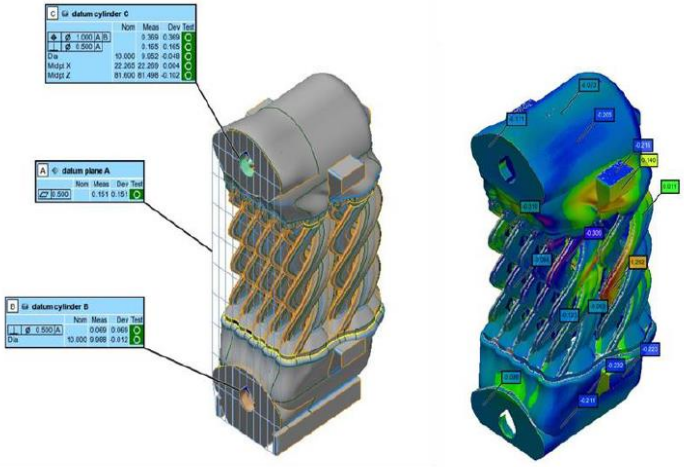
Product verification

Ensures product meets required design specifications and therefore performs as intended

Case study – KHUB-AM-0005 planning for product verification of Heat exchanger produced by Metal PBF-LB
(you have been supplied with this report)



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Planning for Product Verification

- Starts at design concept and process planning stages
- Significant impact on product quality and cost
- Final part inspection at end of manufacturing process is most common method of verifying product quality

BUT

- For complex parts requiring multiple manufacturing operations may be better to verify as manufacturing progresses to;
  - Avoid incurring higher cost /delays later
  - Take timely corrective action
  - Identify the cause of the problem
  - Enable easier access to features (for example in a welded part)

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Strategy for Product Verification

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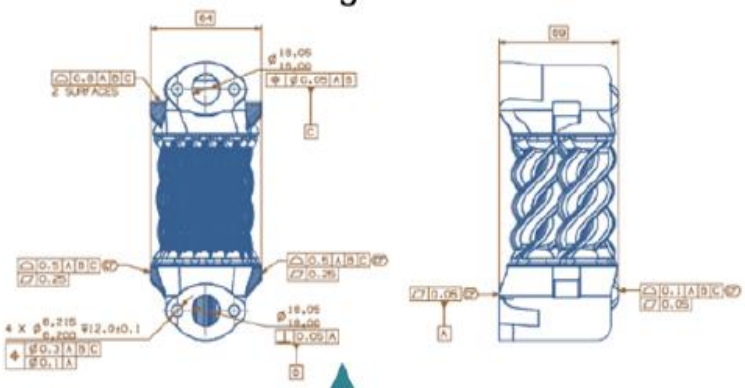
Documents relating to product verification against key product lifecycle steps

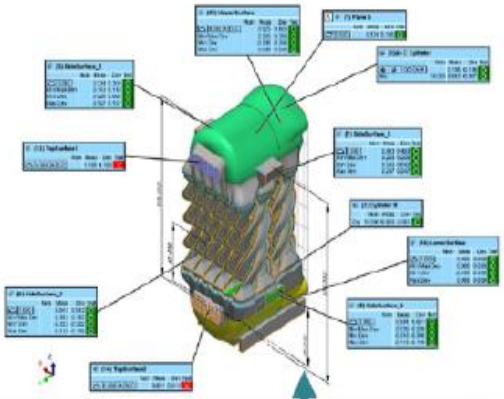
- Functionality statements

Functional requirement	Interpretation	Characteristic type
The component must not interfere with surrounding parts at maximum material condition.	Bounding envelope / maximum material condition.	Form
The interfaces must achieve a strong connection and a good seal.	Threaded flange interface. Control datum features.	Fit
The component must achieve the minimum heat transfer characteristics within its operating volume and conditions.	Heat transfer of xx. Surface area of xx.	Function
The component must achieve the desired hydraulic performance at operating conditions through its life.	Pressure drop vs flow characteristic curve at operating envelope.	Function
Component integrity must be maintained through its life at nominal conditions and at worst operating conditions for a short period.	Operating conditions for xx hours and/or xx heat/cool cycles. Max temperature/pressure for xx hrs. Surface finish of xx worst case for fatigue.	Function

- Drawings



- Inspection programs
- Inspection reports & data



Functionality definition → Process design → Part definition → Inspection planning → Inspection execution

Functional requirements	Verification routes					
	Dimensional	NDT	Condition of supply control	Manufacturing process control	Functional test	In-service history
The component must not interfere with surrounding parts at maximum material condition.	●	○	○	○	○	○
The interfaces must achieve a strong connection and a good seal.	○	○	○	○	○	●
The component must achieve the minimum heat transfer characteristics within its operating volume and conditions.	○	○	○	○	●	○
The component must achieve the desired hydraulic performance at operating conditions through its life.	○	○	○	○	●	○
Component integrity must be maintained through its life at nominal conditions and at worst operating conditions for a short period.	○	○	●	○	●	○

- Verification matrices

Feature	Drawing ref	Sheet/grid ref	System type	Point strategy	Reporting strategy	Feature construction	Comments
1	⌭|0.05|Ⓜ▶|A| 2 SURFACES	1-E12	CMM with scanning tactile probe	Scan around each large hole. 2 scans total.	Report 1 flatness value.	Least squares fit for plane. Treat as continuous feature.	Primary datum feature
2	Ø15.65/16.0Ⓜ▶|B|	1-D10	CMM with scanning tactile probe	2 scans at 1/3 and 2/3 depths.	Report 1 diameter. Report 1 roundness for info.	Least squares fit.	Secondary datum feature
3	⊥|0.05|A▶|D|	1-D10	CMM with scanning tactile probe	Measured above.	Report 1 perpendicularity.	Software mode set to ASME Y14.5	Secondary datum feature
4	Ø15.65/16.0Ⓜ▶|C|	1-H10	CMM with scanning tactile probe	1 scan at middle depth.	Report 1 diameter. Report 1 roundness for info.	Least squares fit.	Tertiary datum feature
5	⌖ Ø0.05|A|B|▶|C|	1-H10	CMM with scanning tactile probe	Measured above.	Report 1 position.	Software mode set to ASME Y14.5	Tertiary datum feature
6-9	4xØ6.215/6.200	1-D6	CMM with scanning tactile probe	1 scan at middle depth.	Report diameter values. Hole at 5 o'clock is no. 1 then number holes clockwise.	Least squares fit.	

- Inspection plans

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Functionality statements

Recommended that document with the following minimum information is created:

1. **Functional requirements**: high level qualitative statements of the intended part function;
2. **Interpretation**: high level quantitative expressions of how the functional requirements will be translated into specifications;
3. **Characteristic type:** whether the functional requirement relates to form, fit or function;
4. **Criticality:** an assessment of relative criticality or importance

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Question ?

What is/are the function requirements of a heat exchanger ?

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Some of the functional requirements for heat exchanger…

Functional requirement	Interpretation	Characteristic type	Criticality
The component must not interfere with surrounding parts at maximum material condition.	Bounding envelope / maximum material condition.	Form	
The interfaces must achieve a strong connection and a good seal.	Use threaded flange interface. Make mating surfaces datum features.	Fit	Critical
The component must achieve the minimum heat transfer characteristics within its operating volume and conditions.	Minimum heat transfer coefficient. Minimum surface area.	Function	Critical
The component must achieve the desired hydraulic performance at operating conditions through its life.	Pressure drop vs flow characteristic curve at operating envelope.	Function	Critical

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Verification matrix

Methods for assessing each requirements is met;

- Dimensional inspection or non-destructive testing (NDT).
- Condition of supply checks - ensuring a valid and traceable CoC (certificate of conformity) has been provided by the supplier.
- Manufacturing process controls - ensuring the process is stable and fixed.
- Functional testing

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Verification matrix for heat exchanger

different colours represent the different methods, and the icons represent whether a requirement is fully or partially met.

Functional requirements	Possible verification routes					
	Dimensional	NDT	Condition of supply	Manufacturing	Functional test	In-service history
The component must not interfere with surrounding parts at maximum material condition.	Measure linear dimensions or profile of external surface.			Prove process is capable.	Go/nogo fixture. Assembly success/failure.	
The interfaces must achieve a strong connection and a good seal.	Thread go/nogo gauge. Measure mating surfaces.	Visually check thread damage. Presence of correct sealant.	Verify screws / inserts are in spec.	Torque settings locked. Calibrated wrenches.	Leak test. Fatigue / vibration test.	
The component must achieve the minimum heat transfer characteristics within its operating volume and conditions.	Measure profile of a surface.	Measure surface area. Measure Sa of internal & external surfaces.	Verify powder is in spec.	Process proved stable. KPVs controlled.	Power test.	Use proven part family design elements.
The component must achieve the desired hydraulic performace at operating conditions through its life.				Process proved stable. KPVs controlled.	Pressure test.	Use proven part family design elements.
Component integrity must be maintained through its life at nominal conditions and at worst operating conditions for a short period.	Verify wall thickness.	Sa of internal & external surfaces. Defect / porosity allowances.	Verify powder is in spec. Material spec.	Lock down build programs.	Accelerated fatigue test. Max temperature test. Max pressure test.	Use historical data from part family if available.
The component's internal surfaces must have antifouling properties to avoid performance degradation.		Sa or feature based characteristics of internal surfaces.		Prove at FAIR and lock down.	Chemical lab tests for product family	Use historical data from part family if available.
The component's external surfaces must be self-cleaning to avoid performance degradation.		Sa or feature based characteristics of external surfaces.		Prove at FAIR and lock down.	Chemical lab tests for product family	Use historical data from part family if available.
The component should be designed in such a way as to not trap powder as this can damage the hydraulic system	Measure profile of surface (external features).	Scan part for presence of powder.		CAD interrogation tools. Machine cleaning / maintenance schedule	Part contamination test.	

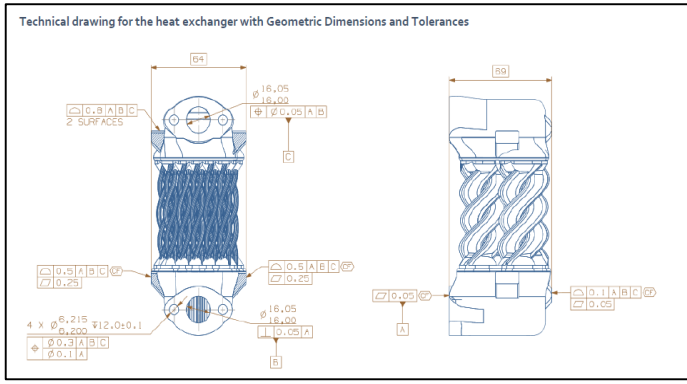
Legend:

Manual gauging / visual	C
3D Structured Light	F
X-Ray CT	T

- Choosing the appropriate combination of verification routes from the matrix, should be based on minimising risk, or maximising the component's functionality, within the given cost and practicality constraints.
- For the heat exchanger example, we can see that, as a minimum, functional testing, X-ray computed tomography, and 3D structured light methods should be used to verify the component. It is notable that verification in this case will be heavily reliant on functional testing.

Part definition and inspection planning

- Part definition refers to the creation of drawings and GD&T (geometric dimension & tolerancing) , following from the definition of the general geometry.
- For a single AM component the following drawings could be created:
  - As-built part
  - Following the removal of supports
  - Post-heat treated condition
  - After finishing



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Inspection planning

creating the overall strategy for the inspection of every feature or requirement in the drawing (such as drawing notes or referenced specifications)

The inspection plan should include the following information:

- Part number;
- Drawing name and version;
- Feature description and feature grid reference or number;
- Inspection system to be used;
- Measurement strategy to be used;
- Feature construction strategy or algorithm to be used;
- Feature reporting strategy.

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Sources of information

Source	Information
Standards reviewed related to these topics	• AWSD20.1/D20-Specification for fabrications of metal components using Additive Manufacturing • SAE AS7032 - Additive Manufacturing Machine Qualification – (Draft copy) • SAE AS7007 – Electron Beam Melting material specification- Aerospace Specification • NASA MSFC-SPEC-3717 - Specification for control and qualification of laser powder bed fusion metallurgical processes • NASA MSFC-SPEC-3716 - Standard for additively manufactured spaceflight hardware by laser powder bed fusion in metals • ISO/ASTM 52942 - Additive manufacturing Qualification principles — Qualifying machine operators of metal powder bed fusion machines and equipment used in aerospace applications (currently being prepared) • ISO/ASTM 52904 or ASTM F3303 - New Guide for Additive manufacturing Guideline for Installation, Operation and Performance Qualification (IQ/OQ/PQ) of Laser-Beam Powder Bed Fusion Equipment for Production Manufacturing (currently going through approval) • ESA - ECSS-Q-ST-70-80C Draft 1 Processing and quality assurance requirements for metallic powder bed fusion technologies for space applications • DIN SPEC 17071 Additive manufacturing - Requirements for quality-assured processes at additive manufacturing centres • AIA (Additive Manufacturing Working Group) Recommended Guidance for Certification of AM Component
Guidelines	• Lloyds Register, - Guidance notes for the Additive Manufacturing certification • MASAAG Guidance note on the Qualification and Certification of Additive Manufactured Parts for Military Aviation • European Federation for Welding, Joining and Cutting Guideline for European/International Operator Powder Bed Fusion – Laser Beam

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Mentimeter - Practice question

Practice questions: Day3-Q2

PQ2 – Product Verification Matrix

In the context of product verification what is CoC an abbreviation for (select only ONE answer)?

1 Clash of clans

2. Code of conduct

3 Certification of conformance

4 Combat operations centre

A. 3-Certificate of conformance

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Next

- End of course questionnaire –see link in chat
- Important guidance for answering the survey

Section 1

- **Q4 -** Where is the training course taking place? **> answer where <u>you</u> are based**

Section 2

- **Q8 –**which pilot course did you attend **- <u>CU 63 CQS for AM</u>**
- **Q10 –** what is the regime of the pilot course **– E'learning**

As we <u>don't</u> have any practical training or assessment for the course……

Q11 (e) Equipment for practical training **= not applicable N/A**

Q12 (e) and (f) = not applicable N/A

Once you have complete the survey you can have a short break

We will be starting the assessment at <u>11:30am</u>

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www.skills4am.eu

Thank you

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SECTOR SKILLS STRATEGY IN ADDITIVE MANUFACTURING

IRISH MANUFACTURING RESEARCH

NATIONAL CENTRE ADDITIVE MANUFACTURING

mtc Manufacturing Technology Centre

WELCOME

Title: Certification, Qualification and Standardisation in Additive Manufacturing

Time: 10.00 to 12.00
Dates: 30th June 2021, 7th July 2021, 14th July 2021 (09.00 – 12.00)
Location: Online

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SECTOR SKILLS STRATEGY
IN ADDITIVE MANUFACTURING

Classroom Etiquette

- Mobile phones on silence please.
- Mute yourself until asked to join discussions.
- Put you hand up if you have a question.
- Write questions into the chat.
- Personal emails & distractions on hold until after training.

THANK YOU

LET'S ENJOY THIS

TRAINING TOGETHER!

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SECTOR SKILLS STRATEGY
IN ADDITIVE MANUFACTURING

Trainers

Katrina Farrell
Learning and Development Specialist
Irish Manufacturing Research

DAY 1 to DAY 3
SAM – Learning Support

Fergal Finn
Manager Standards
Innovation, Policy & Business Development
National Standards Authority of Ireland

DAY 2
SAM - Technical Support

Tristan McCallum
Advanced Manufacturing
Applications Engineer
Irish Manufacturing Research

DAY 2
SAM – Technical Support

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DAY 1

10.00 - 12.00	TRAINING
10.45 – 10.55	BREAK 10 MINS
10.55 – 11.45	TRAINING
11.45 – 12.00	QUIZZ /Q&A

1

DAY 2

10.00 – 12.00	TRAINING
10.45 – 10.55	BREAK 10 MINS
10.55 – 11.45	TRAINING
10.45 – 12.00	QUIZZ/Q&A

2

DAY 3

10.00-12.00	TRAINING
10.45 – 10.55	BREAK 10 MIN
10.55 – 11.45	TRAINING
10.45 – 12.00	QUIZZ/Q&A

3

DAY 2
PART 1

2

10.00
LEARNING OUTCOMES

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SAM

SECTOR SKILLS STRATEGY IN ADDITIVE MANUFACTURING

Project No. 601217-EPP-1-2018-1-BE-EPPKA2-SSA-B

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Learning Outcomes Day 2

LO3 Describe Standardisation in Additive Manufacturing.

LO4 Differentiate and classify the linkages between CQ&S.

LO5 Outline CQ&S activities and identify the main differences associated with each one.

LO6 Recognise the standards which are applicable to AM.

LO7 Research, select and find the relevant AM standards in the public repository.

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DAY 2
FERGAL FINN NSAI

STANDARDS IN AM

2

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CU 63 Syllbus: Topic Summary

Standardisation in AM

Introduction to standards and standardisation.

Additive Manufacturing in standardisation (standardisation bodies).

Areas covered by Technical Committees.

Development of standards.

AM standards and standardisation activities navigation.

Relationship between standardisation with qualification and certification.

Relationship between AM Standards and the AM enabled process chain.

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Day 2

LEARNING OUTCOMES

SAM PROJECT

STANDARDS IN AM

CASE STUDY IN APPLICATION

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Today's breakdown of topics

- What are Standards
- Standards in AM
- Types of Standards
- Benefits of Standards
- Standards Organisations
- Type of Deliverables
- Development Stages
- Member Benefits
- Standards Organizations for Am
- Structure
- National AM Standards
- Irish Mirror Committee
- Our Role
- Get Involved

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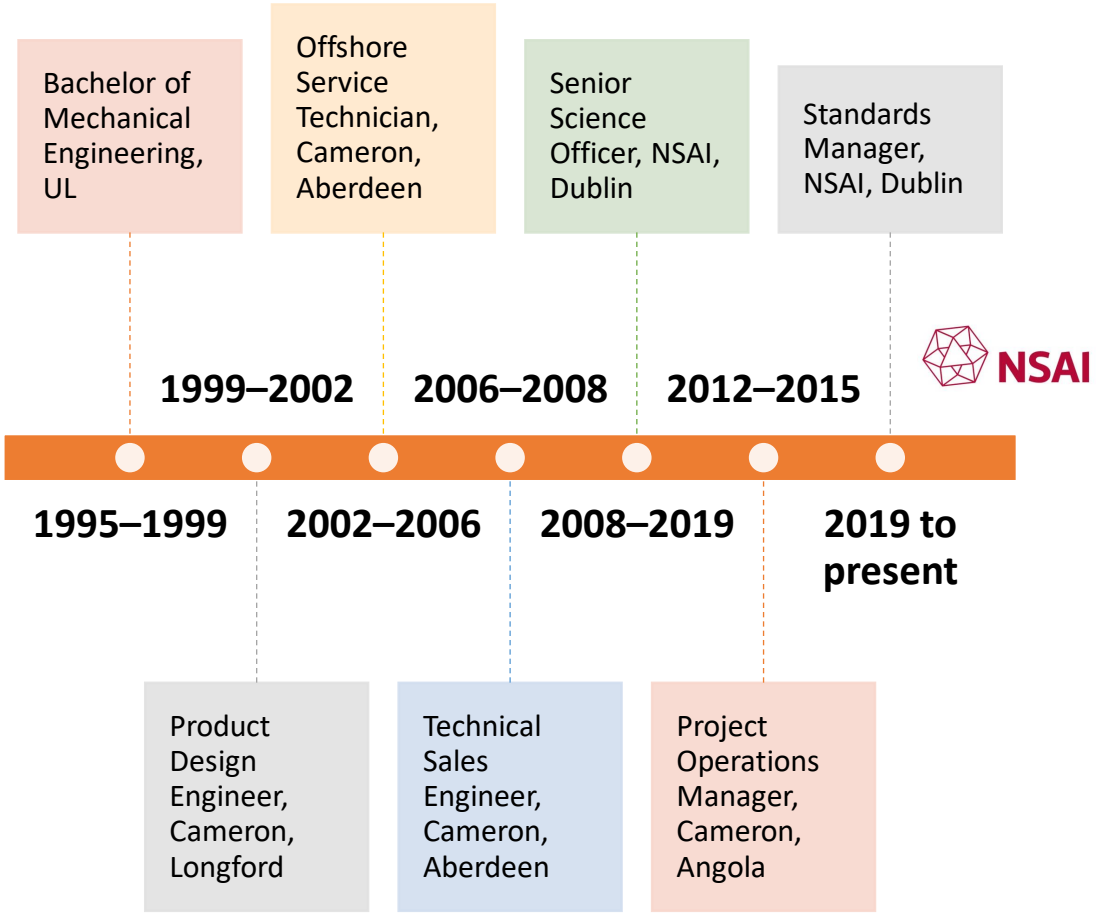
Who is Fergal Finn?



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Who is NSAI?

Government Agency – promoting the development, use and compliance with National, European and International Standards and European Directives

NSAI Act 1996

Acts on behalf of the Minister for Enterprise, Trade & Employment

An Roinn Fiontar, Trádála agus Fostaíochta
Department of Enterprise, Trade and Employment

NSAI
National Standards Authority of Ireland

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Who is NSAI?

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The hierarchy

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The hierarchy – Regulation (Road vehicles)

RSA

Road Safety Authority

Regulations for vehicles & trailers in service

UNECE

United Nations Economic Commission for Europe

World Forum for Harmonization of Vehicle Regulations (WP.29) is a unique worldwide regulatory forum

European Commission

Directives and regulations on motor vehicles, their trailers, systems and components

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The hierarchy - Standards

I.S EN ISO 4254-1:2015
Agricultural machinery - Safety - Part 1: General requirements (ISO 4254-1:2013)

I.S EN 15694:2009+A1:2015
Agricultural and forestry tractors - Passenger seat - Requirements and test procedures

I.S. EN ISO 16231-2:2015
Self-propelled agricultural machinery - Assessment of stability - Part 2: Determination of static stability and test procedures (ISO 16231-2:2015)

I.S. EN 15695-1:2009
Agricultural tractors and self-propelled sprayers - Protection of the operator (driver) against hazardous substances - Part 1: Cab classification, requirements and test procedures

ISO 22172-2:2021
Agricultural vehicles — Standardized access to repair and maintenance information (RMI) — Part 2: Vehicle on-board diagnostics

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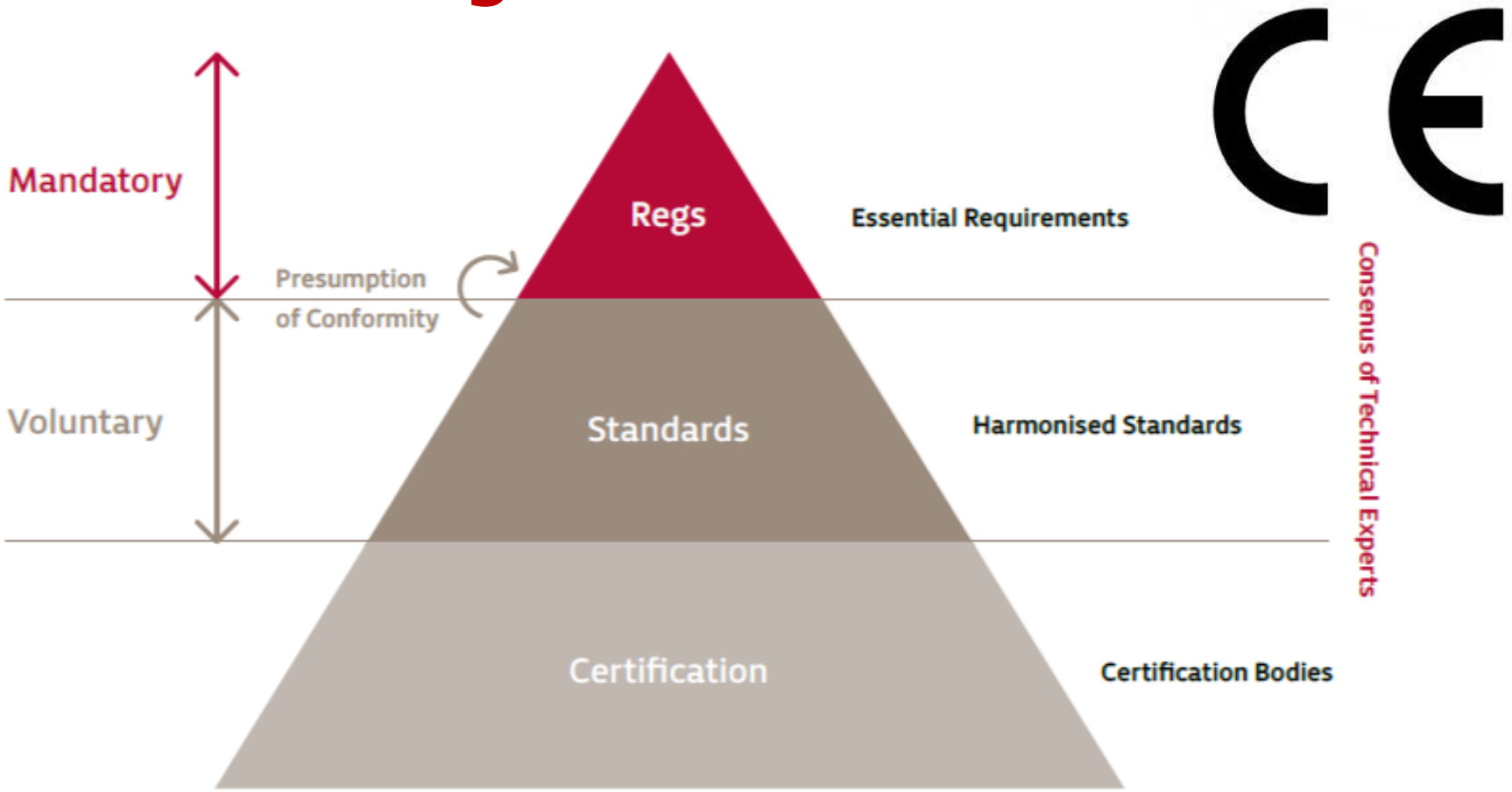
EU New Legislative Framework



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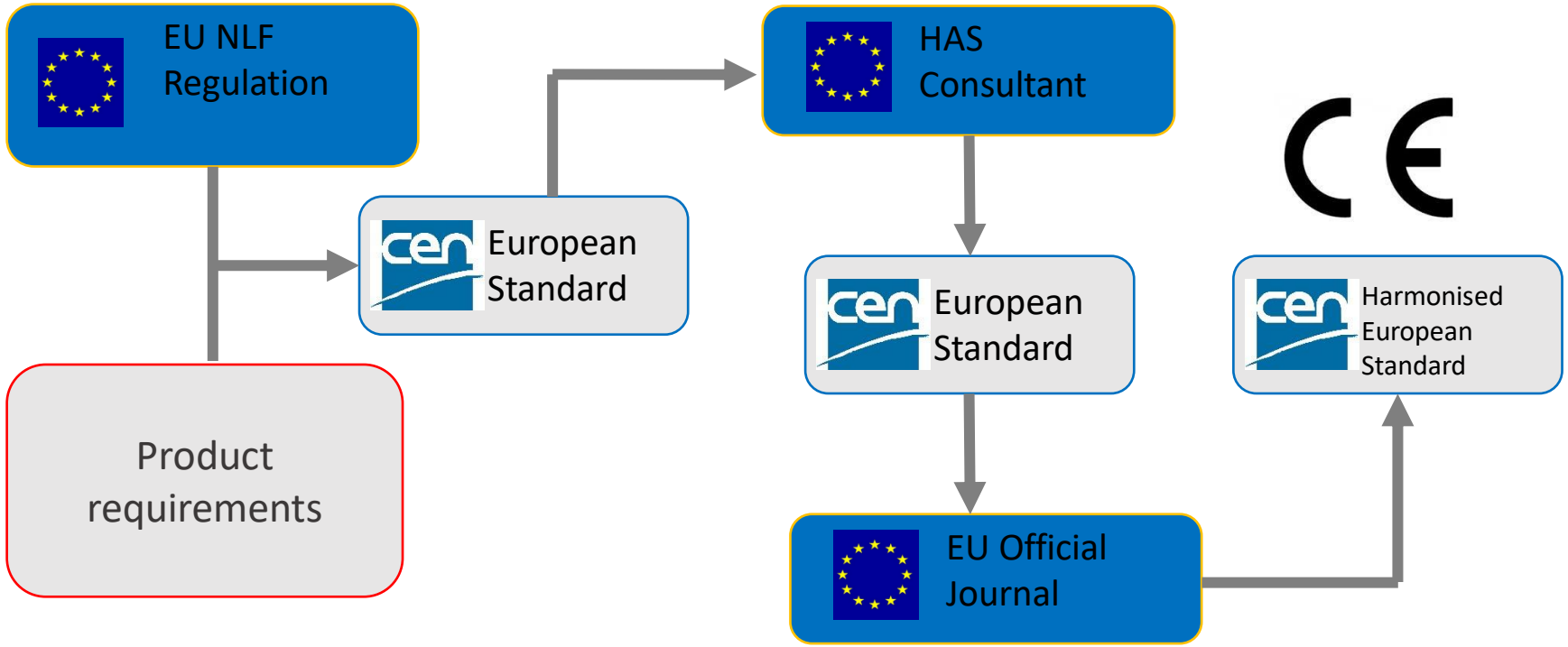
European Harmonised Standards



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Certification

Conformity Assessment

- IAF – International Accreditation Forum
- Conformity Assessment Accreditation Bodies

Accreditation Body

- INAB, Irish National Accreditation Board
- Accreditation for Certification Bodies

Certification Body

- NSAI (Medical Devices)
- Certification

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European Conformity (Medical Devices Regulation)

Regulation

- EU New Legislative Framework (Regulations)
- New Approach Directive

Competent Authority

- HPRA (MDR IVDR)
- Designating Authority
- Market Surveillance Authority

Notified Body

- NSAI (Medical Devices) CE
- Certification

EU Regulation 2017/745

NSAI

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European Conformity – RAPEX

Safety Gate: the EU rapid alert system for dangerous non-food products

Alert number: A11/00044/21

Published on 10/06/2021 in web report Report-2021-24

Print | Back to report

Risk type	Burns
Notifying country	Hungary
Alert number	A11/00044/21

The product is attractive to children. A child may touch the accessible hot heating surface of the product and suffer burns.
The product does not comply with the requirements of the Low Voltage Directive and the relevant European standard EN 60335.

Category	Electrical appliances and equipment
Product	Popcorn maker

Hide details of the product

Description

Red plastic covered popcorn machine in the shape of a retro popcorn maker trolley with a see-through window. The product was also sold online.

Packaging description

Colourful cardboard box.

Brand

mikamax

Name

POPCORN MACHINE

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The commerce of manufacturing

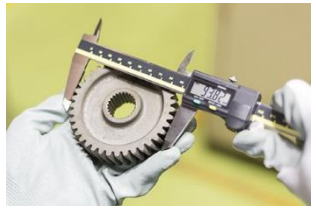
Raw material

ASTM A291 – Steel Forgings, Carbon and Alloy, for Pinions, Gears and Shafts for Reduction Gears

Manufacture

ISO 9606-1:2012 Qualification testing of welders

Inspection



ISO 3452-1:2013 Non-destructive testing - Penetrant testing

ISO 9934-1:2016 Magnetic particle testing

ISO 16809:2017 Non-destructive testing - Ultrasonic thickness measurement

Product

~~Assembly~~

ISO 21771:2007 Gears – Cylindrical involute spur and gear pairs

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What are Standards?

‘Standard’ means a technical specification, adopted by a recognized standardization body, for repeated or continuous application, with which compliance is not compulsory.

European regulation on standardization (1025/2012)

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What are Standards?

A standard is:

- voluntary in application
- established by all interested parties
- **consensus** based
- approved by a recognized body
- meant for a common and repeated use

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Development Principles of Standards?

Market need

Global expert opinion

Transparency

Impartiality & consensus

Open to all stakeholders

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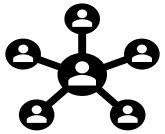
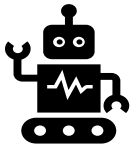
Benefits of Standards

Assist trade by eliminating technical barriers



Promote interoperability of products & services



Promote new technologies & good practices – spread knowledge

Increase safety of products & protect health, environment etc and protecting the consumer

Assist with compliance with legal obligations

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Everyday standardisation

1973: First Mobile Phone

I.S. EN IEC 62684:2018 (edition 2)
Interoperability specifications of common external power supply (EPS) for use with data-enabled mobile telephones now exists (excluding Apple)

IEC

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International Standards Organizations

International Organization for Standardization

Technical, Services, Energy, Healthcare, Food…

International Electrotechnical Commission

Electricity and Electrotechnical

International Telecommunications Union

Electronic Communications

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European Standards Organizations

European Committee for Standardization
Technical, Services, Energy, Healthcare, Food…

European Committee for Electrotechnical Standardization
Electricity and Electrotechnical

European Telecommunications Standards Institute
Electronic Communications

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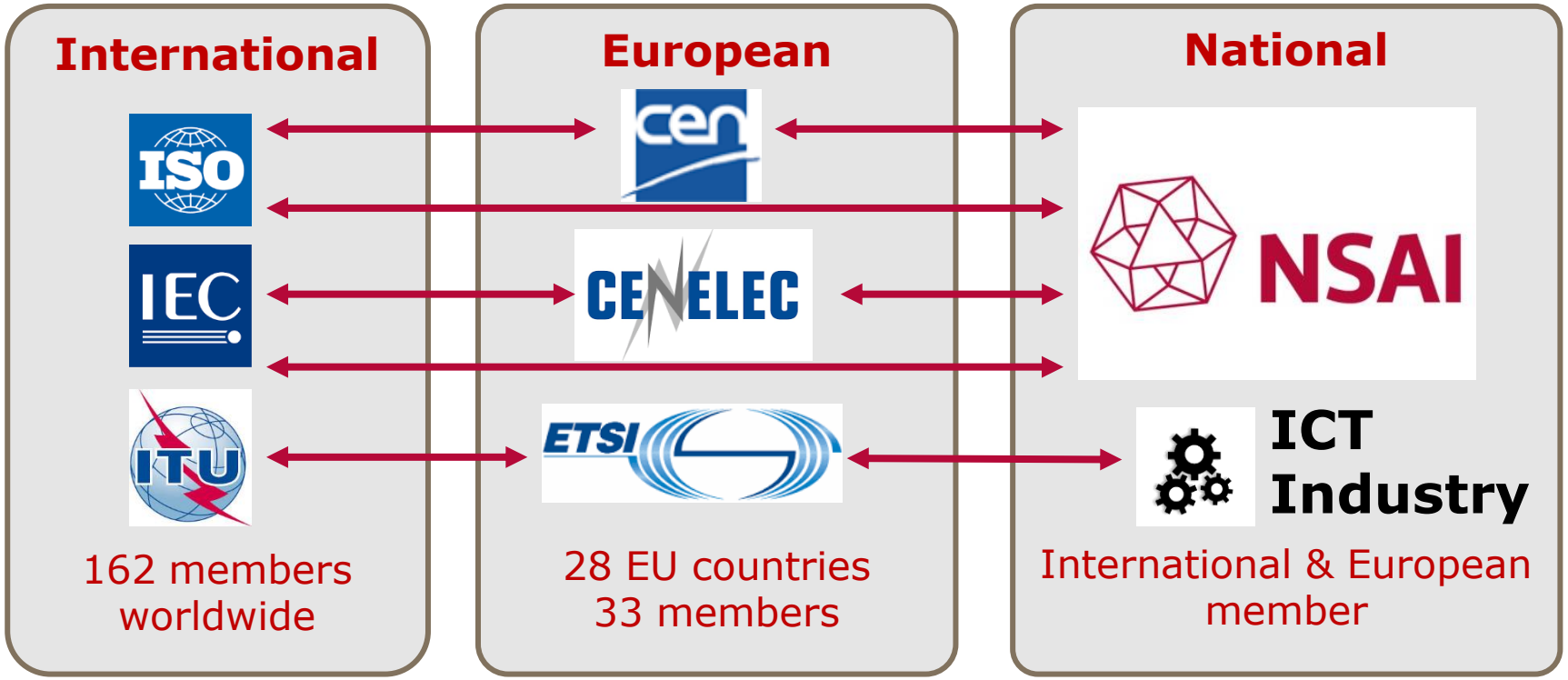
The Standards highway



Process relationships between the Standards Organizations

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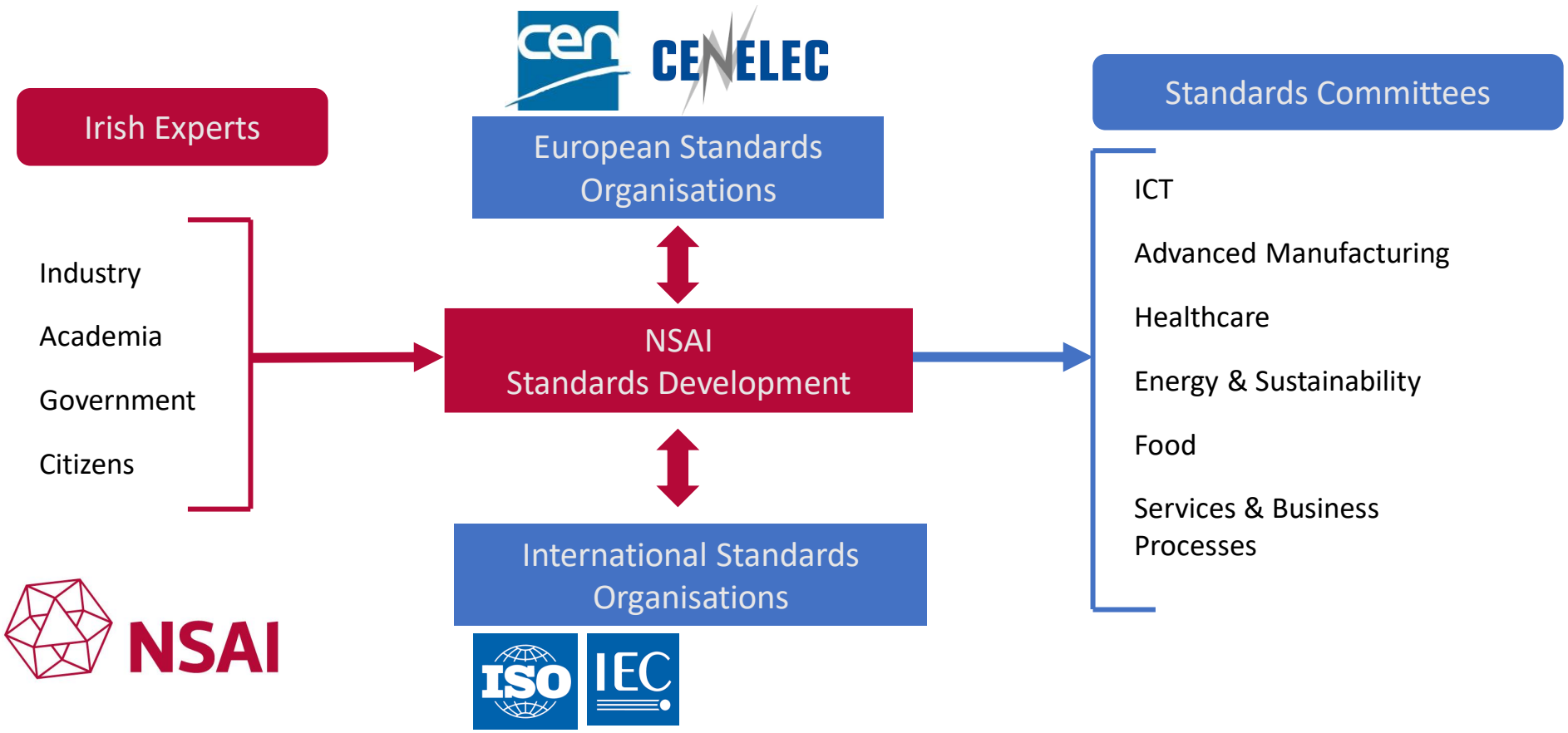
Our role – Connect & Facilitate



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Types of Standards

4 major types

Management System Standards

describe the functions and structure/relationships within an organisation.

ISO 9001- Quality Management Systems - Requirements

Product Specification Standards

define characteristics of a product or service with performance thresholds

ISO 17296-2:2016 – Additive manufacturing - General principles - Part 2: Overview of process categories and feedstock

Fundamental Standards

Terminology, signs, symbols etc.

ISO 52900:2015 – Additive manufacturing – General principles – Terminology

Test Methods

detail test and analysis methods for products

ISO 9934:2015 – Non-destructive testing – Magnetic particle testing

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Management system standards

- ISO 9001 – Quality Management System
- ISO 27001 – Information Security Management
- ISO 14000 – Environmental Management
- ISO 50001 – Energy Management
- ISO 45001 – Occupational health and safety
- ISO 56000 – Innovation management
- ISO 42000 – Artificial Intelligence Management System (coming soon)

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Types of deliverables – ISO/CEN

Type of Deliverable	ISO/IEC
Standard – **EN/ISO/IEC**	**ISO/IEC –** Approved by members, consensus on rules, characteristics or results for optimum order in a given context – consensus achieved
Technical Specification - **TS**	**ISO TS** – Topic under technical development – possibility of a future International standard – not full consensus
Technical Report - **TR**	**ISO TR** - Data or information on perceived "state of the art" e.g. informative report or survey results. Informative

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Development stages

Comparing development processes for an IS

	6 stages	Action	Balloting time	Default path	Shortest path
1	Proposal NP	Proposal to start a new project	• 3-month ballot by default • 2-month ballot possible • TC/SC resolution for revision & amendments	NP	NP Straight to DIS
2	Preparatory WD *	Expert consensus within working group		WD	
3	Committee CD *	Committee consensus	• 2-month ballot by default • 3 or 4 month vote possible • Can be skipped	CD	
4	Enquiry DIS	National consensus	• 2-month translation • 3-month ballot	24 months to reach DIS	12 months to reach DIS
5	Approval FDIS *	YES or NO vote	• Skipped by default • Can be introduced • 2-month ballot	FDIS	
6	Publication	ISO International Standard		Up to 36 months IS	Down to 9 months IS

* OPTIONAL

Sec. Admin. (CIB)

ISOCS Admin.

Stage 10 Proposal

Stage 20 Preparatory

Stage 30 Committee

Stage 40 Enquiry

Stage 50 Approval

Stage 60 Publication

NSAI

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Committee Member benefits

Standards can be part of your Research journey introducing new innovations

You can be part of the Standard as it develops and influence technical aspects

You can be part of a network of like minded experts is a specific technical area

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Standards in Additive Manufacturing

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Standards Organisations

Guiding principles in AM Standardization

One set of AM standards –to be used globally "One world –One Standard"

Work on a common roadmap and organizational structure for AM standard

Use and elaborate upon existing standards, modified for AM purposes when necessary to increase efficiency and effectiveness

ISO/TC 261, ASTM F42 and CEN/TC 438 work together and in the same direction with an emphasis on joint standards development

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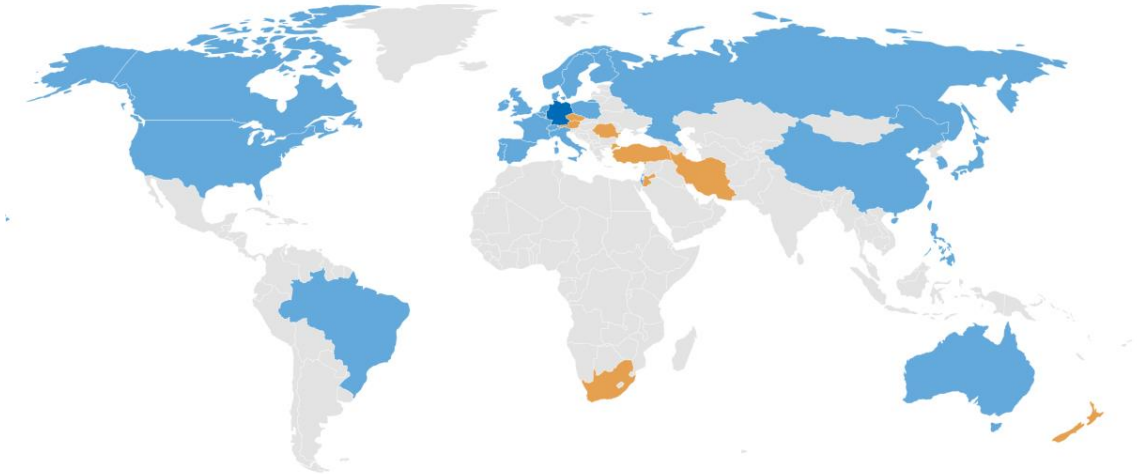
ISO/TC 261 – Additive Manufacturing

ISO Technical Committee 261
Created 2011
- Secretariat – DIN (Germany)
- 26 P-members (including IRELAND)
- 9 O-members

19 Published Standards
35 Standards under development



ISO - ISO/TC 261 - Additive manufacturing

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Structure

ISO/TC 261

ASTM F42

- ISO/TC 261/ WG 1 Terminology
- ISO/TC 261/ WG 2 Methods process and materials
  - JG 55
    - I.S. EN ISO/ASTM 52903-1:2021
    - I.S. EN ISO/ASTM 52903-2:2020
  - JG 56
    - I.S. EN ISO/ASTM 52904:2020
  - JG 58
    - ISO/ASTM CD 52908
  - JG 60
    - ISO/ASTM DTR 52906
  - JG 61
    - ISO/ASTM CD 52909
  - JG 66
    - I.S. EN ISO/ASTM 52907:2019
- ISO/TC 261/ WG 3 Test methods
- ISO/TC 261/ WG 4 Data and Design
- ISO/TC 261/ WG 6 Environmental Health & Safety
- ISO/TC 261/ JWG 10 Aerospace
- ISO/TC 261/ JWG 11 Plastics

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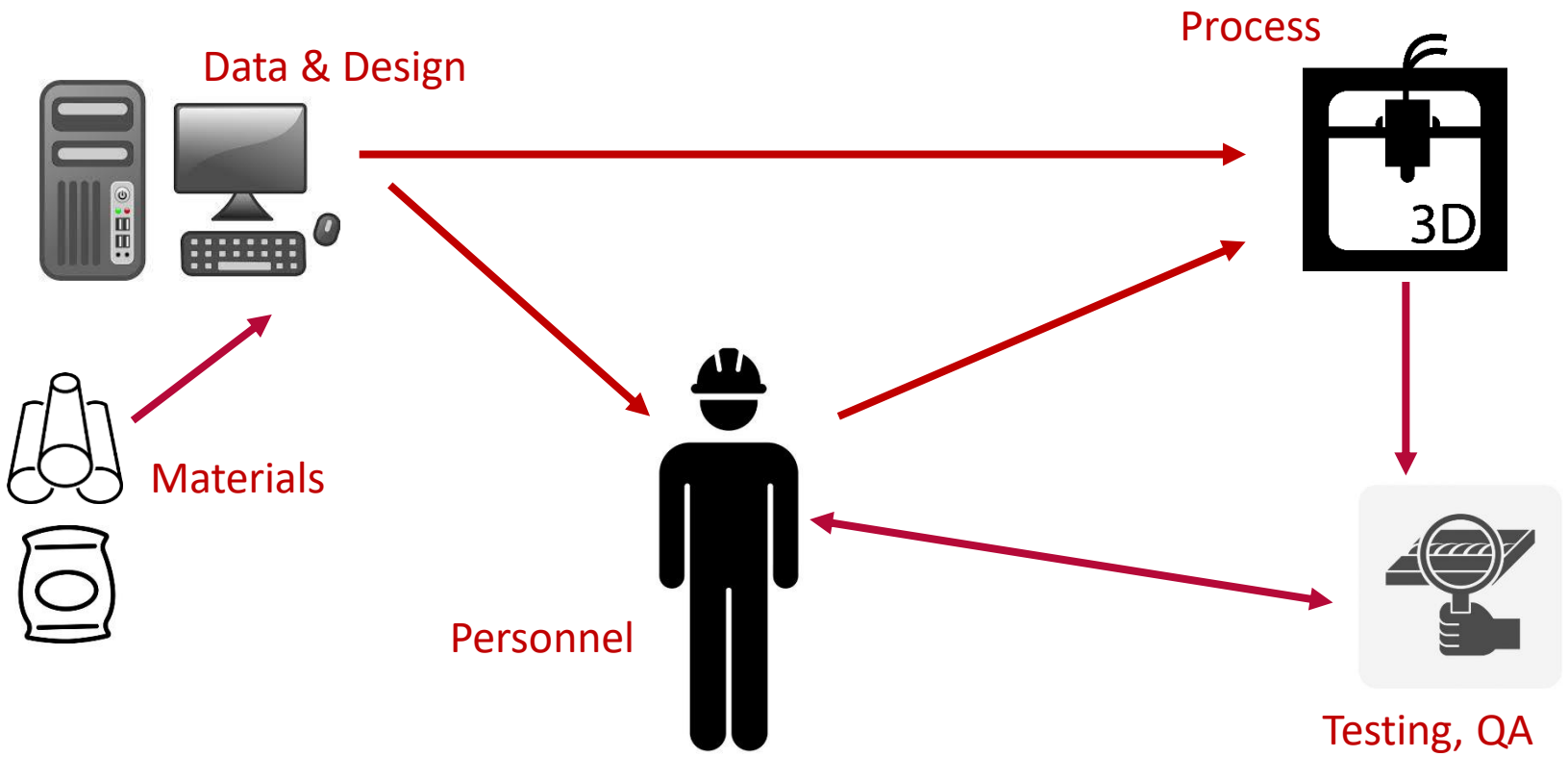
Standards in Additive Manufacturing



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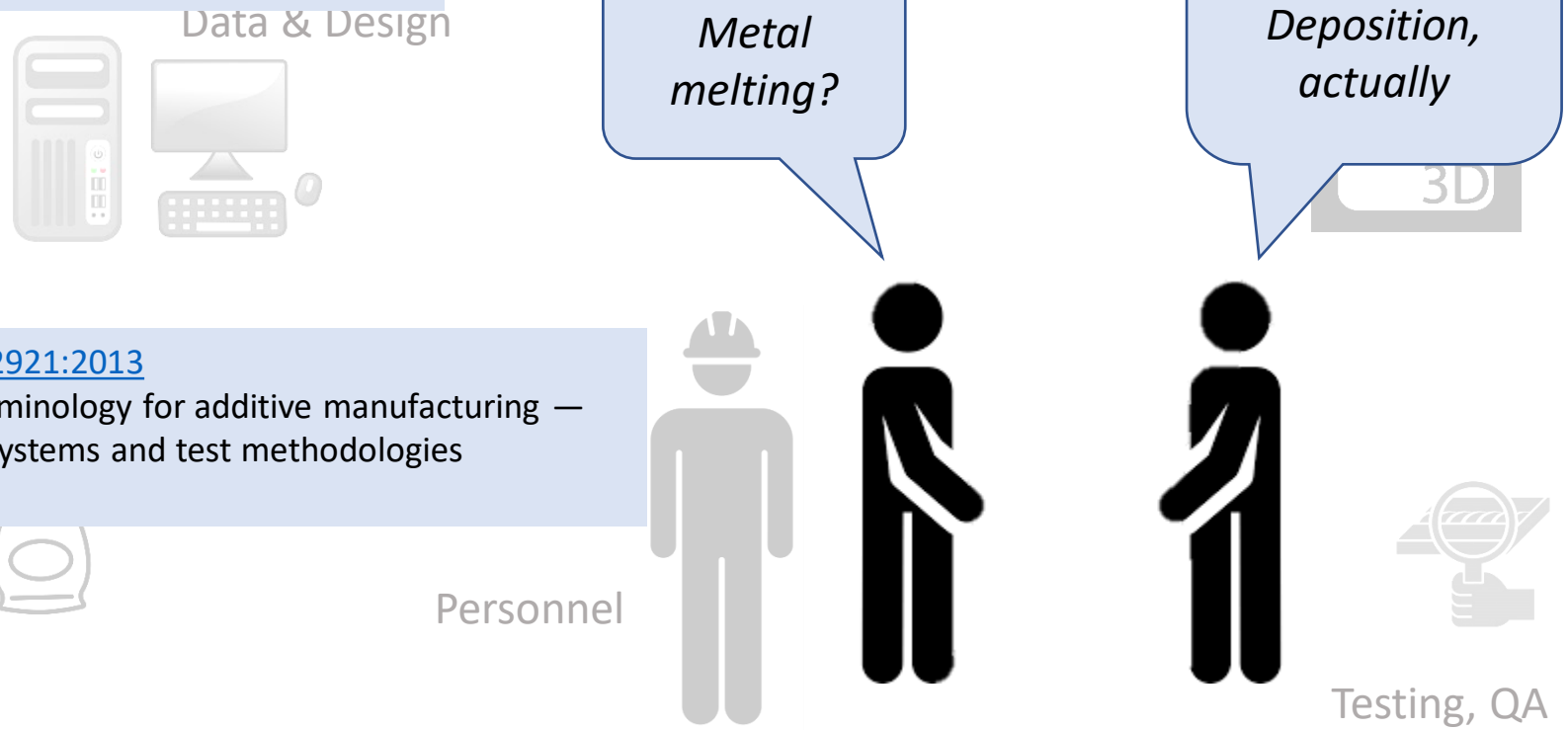
Terminology

ISO/ASTM 52900:2015
General principles — Terminology

ISO/ASTM 52921:2013
Standard terminology for additive manufacturing — Coordinate systems and test methodologies



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Data & Design

Data & Design

Materials

Personnel

Testing, QA

[ISO/ASTM 52910:2018](#)
Design — Requirements, guidelines and recommendations

[ISO/ASTM TR 52912:2020](#)
Design — Functionally graded additive manufacturing

[ISO/ASTM 52911-2:2019](#)
Design — Part 2: Laser-based powder bed fusion of polymers

[ISO/ASTM 52911-1:2019](#)
Design — Part 1: Laser-based powder bed fusion of metals

[ISO/ASTM 52915:2020](#)
Specification for additive manufacturing file format (AMF) Version 1.2

[ISO/ASTM 52950:2021](#)
General principles — Overview of data processing

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Materials

ISO 17296-2:2015
General principles — Part 2: Overview of process categories and feedstock

Process

ISO/ASTM 52903-1:2020
Material extrusion-based additive manufacturing of plastic materials — Part 1: Feedstock materials

Materials

ISO/ASTM 52907:2019
Feedstock materials — Methods to characterize metal powders

ISO 27547-1:2010
Plastics — Preparation of test specimens of thermoplastic materials using mouldless technologies — Part 1: General principles, and laser sintering of test specimens

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Personnel

Data & Design

Process

ISO/ASTM 52942:2020
Qualification principles — Qualifying machine operators of laser metal powder bed fusion machines and equipment used in **aerospace** applications

Materials

Personnel

Testing, QA

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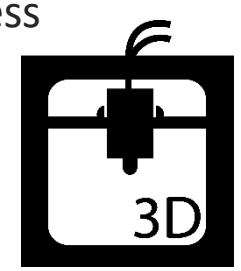
Process

Process



ISO/ASTM 52903-2:2020
Material extrusion-based additive manufacturing of plastic materials — Part 2: Process equipment

ISO/ASTM 52904:2019
Process characteristics and performance — Practice for metal powder bed fusion process to meet critical applications

Materials

ISO/ASTM 52941:2020
System performance and reliability — Acceptance tests for laser metal powder-bed fusion machines for metallic materials for **aerospace** application

Testing, QA

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Test & Inspection

Data & Design

Process

[ISO/ASTM 52902:2019](#)
Test artifacts — Geometric capability assessment of additive manufacturing systems

Materials

[ISO/ASTM 52901:2017](#)
General principles — Requirements for purchased AM parts

Personnel

Testing, QA

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In development

Intentionally seeding flaws in additively manufactured (AM) parts

Anisotropy effects in mechanical properties of AM part

Standard test artifacts

Round robin studies for additive manufacturing

NDT for AM parts

Test methods for characterization of powder flow properties for AM applications

Digital product definition and data management

Extrusion of Plastic Materials

Personnel Training

Requirements for purchased AM parts

Test methods for characterization of powder flow properties

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Irish Standards

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I.S. EN ISO v BS EN ISO

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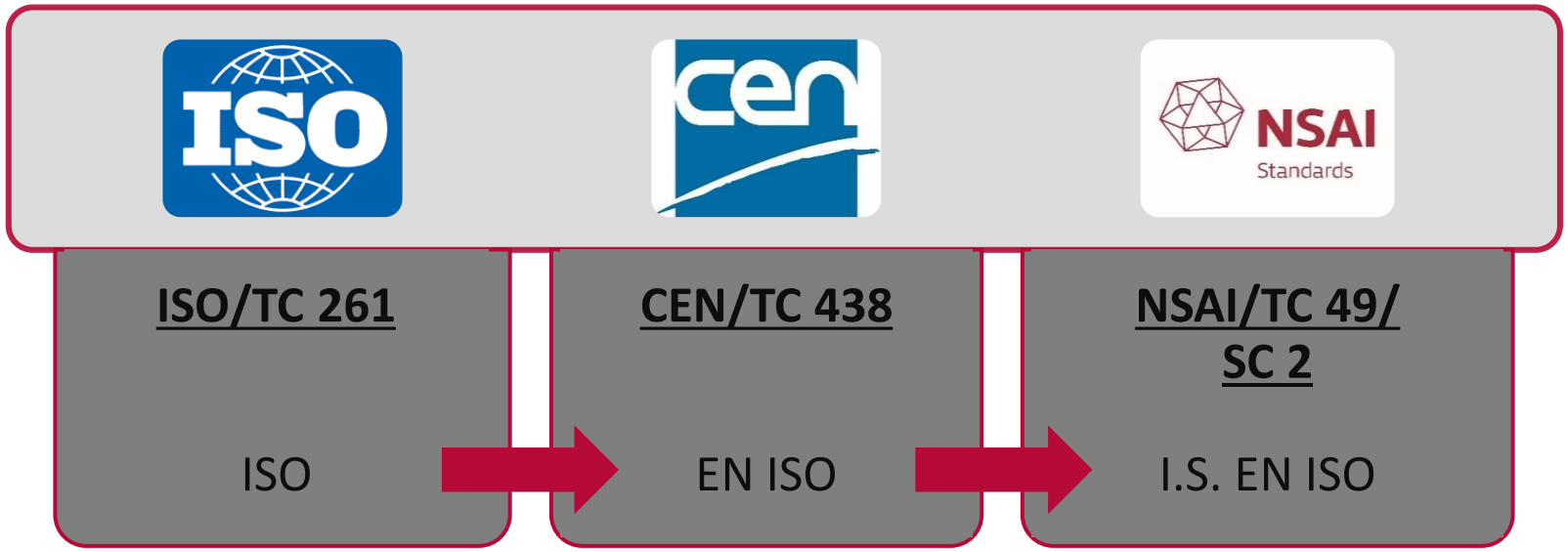
Standards adoption and numbering



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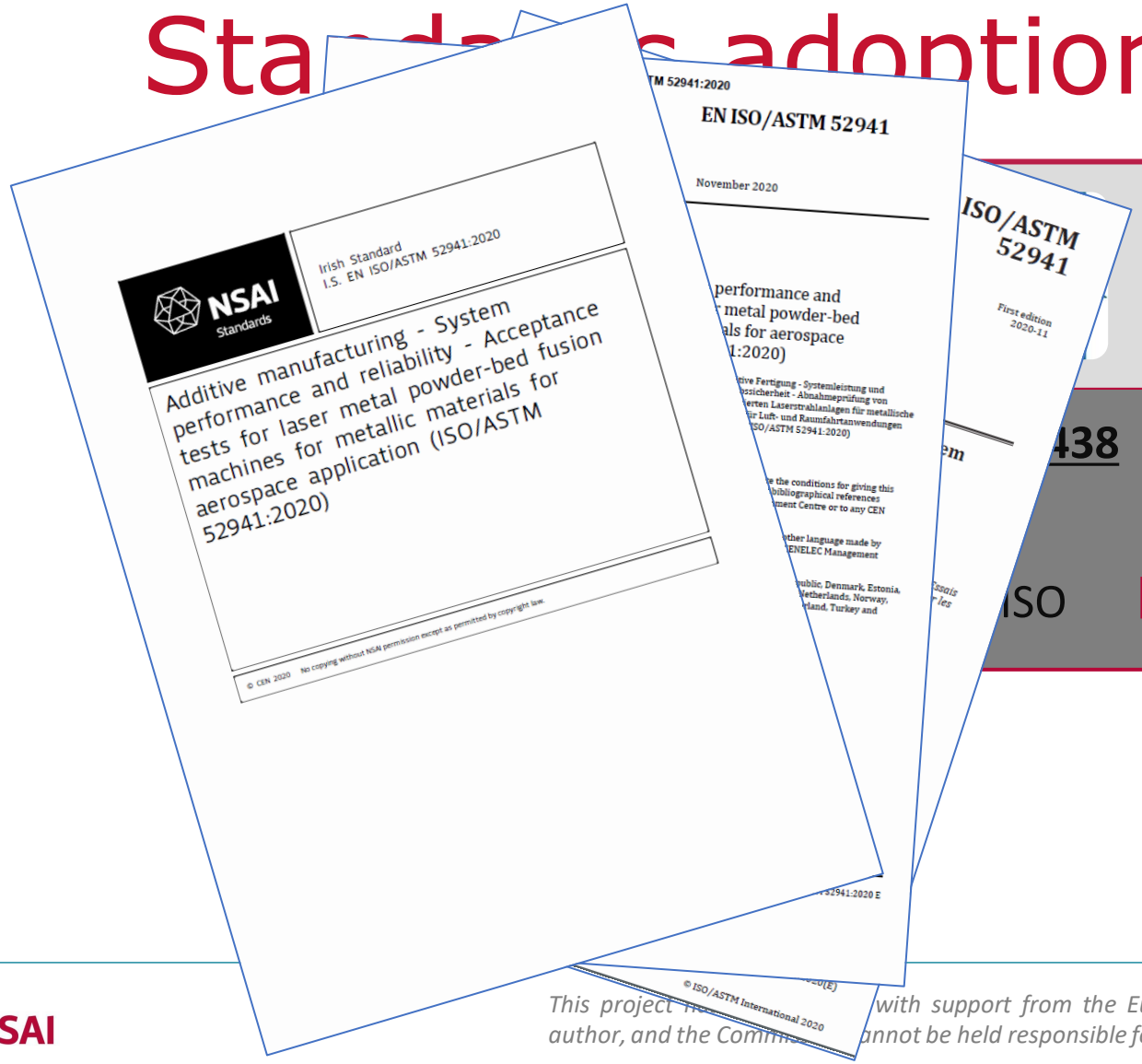
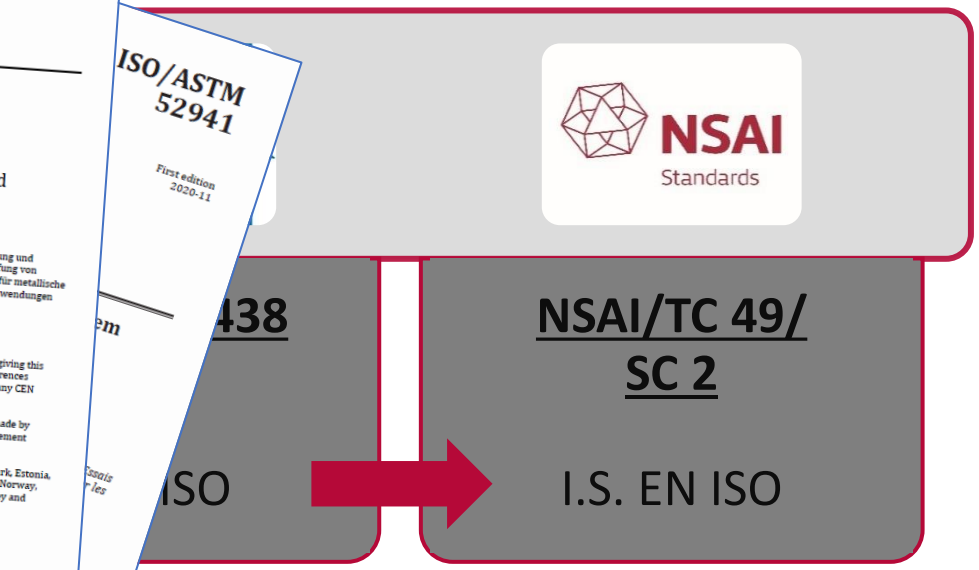
Standards adoption and numbering





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SECTOR SKILLS STRATEGY IN ADDITIVE MANUFACTURING

Co-funded by the Erasmus+ Programme of the European Union

Irish Mirror Committee NSAI/TC 49/SC 2

Rapid Innovation Unit

DCU

SEAM

Trinity College Dublin
The University of Dublin

lpe

Irish Manufacturing Research™
Research & Technology Organisation
Advanced Manufacturing Ireland

Dublin Institute of Technology
Institiúid Teicneolaíochta Átha Cliath
D·I·T

AMBER

NUI Galway
OÉ Gaillimh

UCD DUBLIN

stryker

DePuy Synthes
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

Boston Scientific

I-Form
Advanced Manufacturing Research Centre

IT Sligo
An Institiúid Teicneolaíochta, Sligeach

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

NSAI

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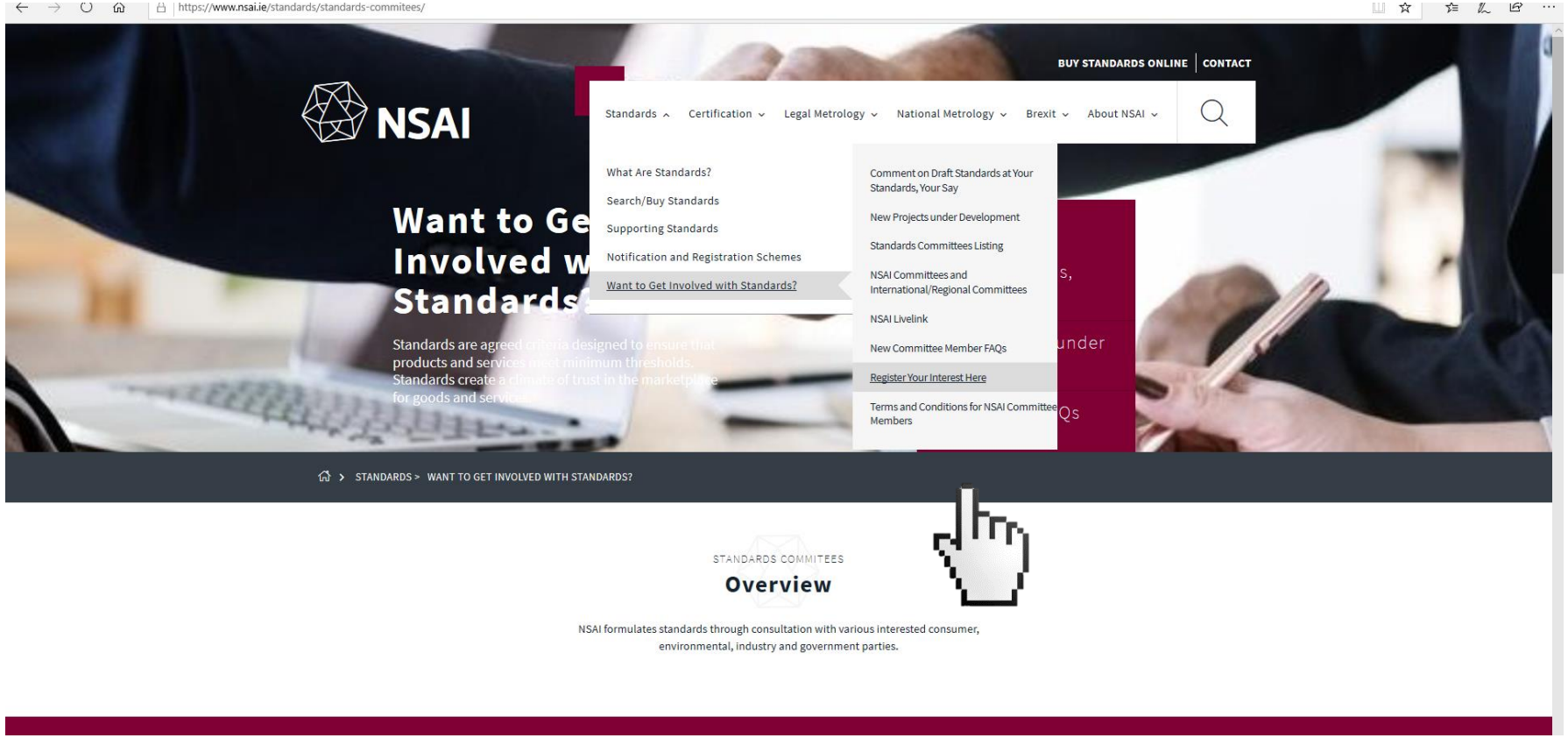
Get involved – NSAI.ie



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Input to draft Standards

Your Standards,
Your Say
Review, Read & Comment on drafts
www.nsainep.ie

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Additional information

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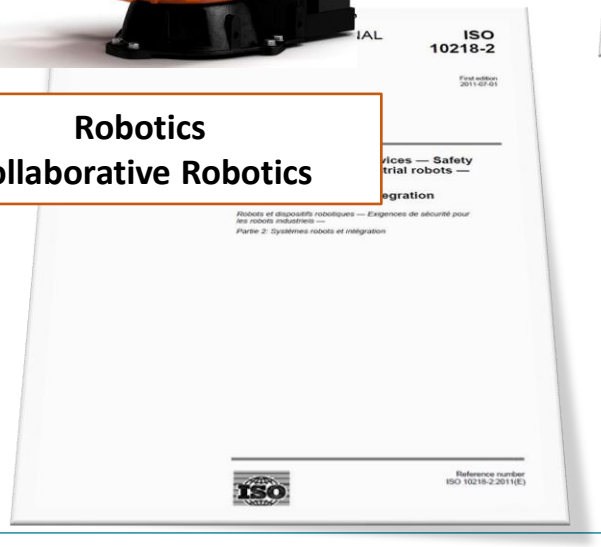
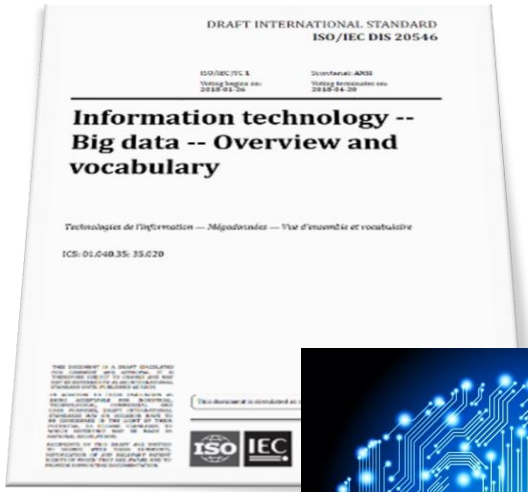
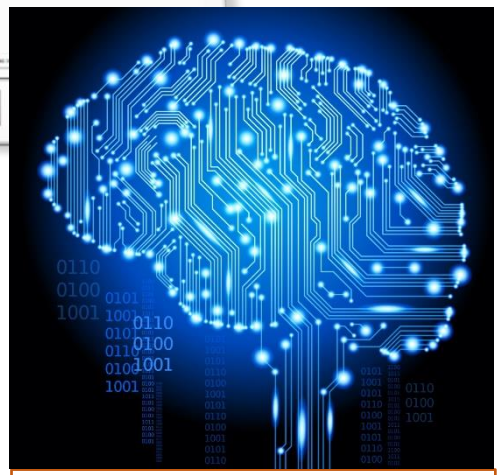
What else is there?

Internet of Things
IoT



Robotics
Collaborative Robotics





Artificial Intelligence
AI

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Standards?

Standards are part of your industry

You can see the Standards as they develop

You can be part of the Standard as it develops

NSAI is here to help you just call Fergal (01) 807 3852

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Thank You.

WWW.NSAI.IE

Fergal.Finn@nsai.ie

Search "NSAI"

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DAY 1
PART 2

1

11.00 – 11.45
Certification and Qualification in AM

.

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Typical Characteristics of Certification and Qualification?

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Criteria	Qualification	Certification
Scope	Process: Evaluating a prototype design/materials/test phase.	Process: Evaluating material/product/component during or at end of development process.
Objective	Prototype meets specified requirements.	Product meets the requirements.
Questions to address	Are we designing/building to requirement?	Right product?
Evaluation Items	Document	Actual product/software

Criteria	Qualification	Certification
Activities	Reviews Audit/site visits Witness testing Compliance statement Facility approvals Technology assessment Manufacturing procedure qualification	Inspections Testing Product certification Material certification
Approval Regime	Approval of manufacturer Type approval Approval of supplier	Approval of manufacturer Type approval Approval of supplier

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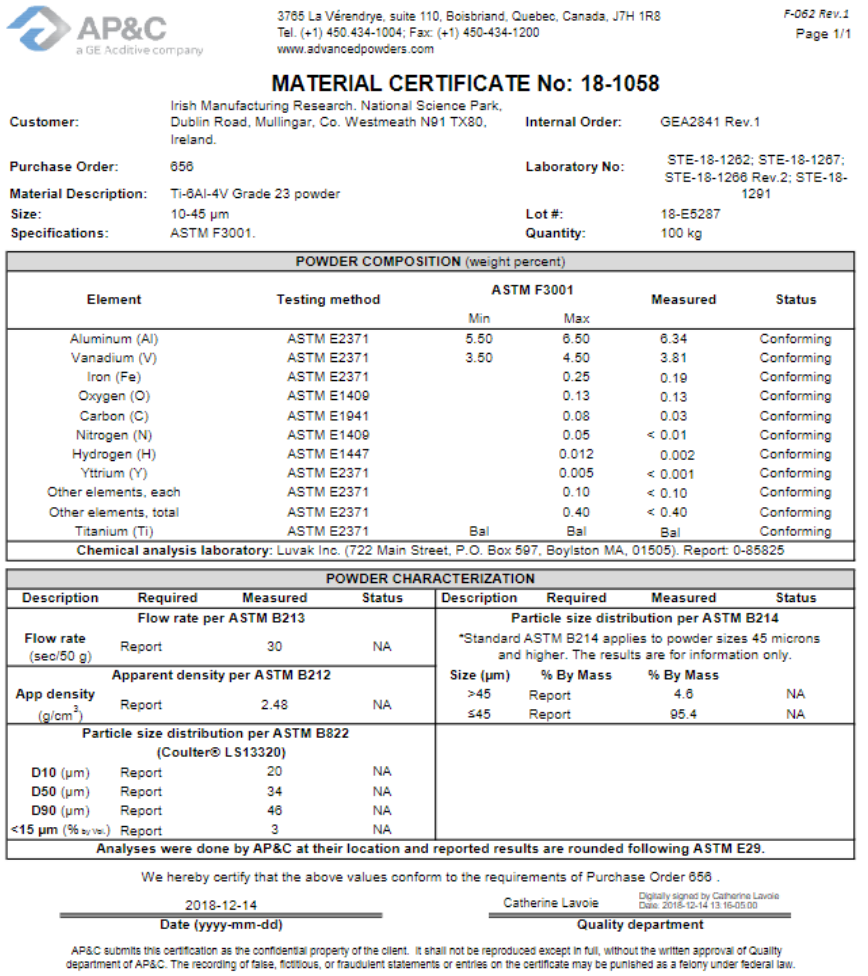
Material Certification

- IMR specified powder
  - Type
  - Morphology
  - Particle size
- AP&C supplied & certified powder
  - Tested to specification using standards



AP&C
a GE Additive company

3765 La Vérendrye, suite 110, Boisbriand, Quebec, Canada, J7H 1R8
Tel. (+1) 450.434-1004; Fax: (+1) 450-434-1200
www.advancedpowders.com

F-062 Rev.1
Page 1/1

MATERIAL CERTIFICATE No: 18-1058

Customer:	Irish Manufacturing Research, National Science Park, Dublin Road, Mullingar, Co. Westmeath N91 TX80, Ireland.	**Internal Order:**	GEA2841 Rev.1
Purchase Order:	656	**Laboratory No:**	STE-18-1262; STE-18-1267; STE-18-1266 Rev.2; STE-18-1291
Material Description:	Ti-6Al-4V Grade 23 powder		
Size:	10-45 µm	**Lot #:**	18-E5287
Specifications:	ASTM F3001.	**Quantity:**	100 kg

POWDER COMPOSITION (weight percent)

Element	Testing method	ASTM F3001 Min	ASTM F3001 Max	Measured	Status
Aluminum (Al)	ASTM E2371	5.50	6.50	6.34	Conforming
Vanadium (V)	ASTM E2371	3.50	4.50	3.81	Conforming
Iron (Fe)	ASTM E2371		0.25	0.19	Conforming
Oxygen (O)	ASTM E1409		0.13	0.13	Conforming
Carbon (C)	ASTM E1941		0.08	0.03	Conforming
Nitrogen (N)	ASTM E1409		0.05	< 0.01	Conforming
Hydrogen (H)	ASTM E1447		0.012	0.002	Conforming
Yttrium (Y)	ASTM E2371		0.005	< 0.001	Conforming
Other elements, each	ASTM E2371		0.10	< 0.10	Conforming
Other elements, total	ASTM E2371		0.40	< 0.40	Conforming
Titanium (Ti)	ASTM E2371	Bal	Bal	Bal	Conforming

Chemical analysis laboratory: Luvak Inc. (722 Main Street, P.O. Box 597, Boylston MA, 01505). Report: 0-85825

POWDER CHARACTERIZATION

Description	Required	Measured	Status
Flow rate per ASTM B213			
Flow rate (sec/50 g)	Report	30	NA
Apparent density per ASTM B212			
App density (g/cm^3)	Report	2.48	NA
Particle size distribution per ASTM B822 (Coulter® LS13320)			
D10 (µm)	Report	20	NA
D50 (µm)	Report	34	NA
D90 (µm)	Report	46	NA
<15 µm (% by Vol.)	Report	3	NA

Description	Required	Measured	Status
Particle size distribution per ASTM B214			
*Standard ASTM B214 applies to powder sizes 45 microns and higher. The results are for information only.			
Size (µm)	**% By Mass**	**% By Mass**	
>45	Report	4.6	NA
≤45	Report	95.4	NA

Analyses were done by AP&C at their location and reported results are rounded following ASTM E29.

We hereby certify that the above values conform to the requirements of Purchase Order 656 .

2018-12-14
Date (yyyy-mm-dd)

Catherine Lavoie
Digitally signed by Catherine Lavoie
Date: 2018-12-14 13:16:05:00
Quality department

AP&C submits this certification as the confidential property of the client. It shall not be reproduced except in full, without the written approval of Quality department of AP&C. The recording of false, fictitious, or fraudulent statements or entries on the certificate may be punished as a felony under federal law.

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Material Description: Ti-6Al-4V Grade 23 powder

1291

Size: 10-45 µm **Lot #:** 18-E5287

Specifications: ASTM F3001. **Quantity:** 100 kg

POWDER COMPOSITION (weight percent)					
Element	**Testing method**	**ASTM F3001**		**Measured**	**Status**
		Min	Max		
Aluminum (Al)	ASTM E2371	5.50	6.50	6.34	Conforming
Vanadium (V)	ASTM E2371	3.50	4.50	3.81	Conforming
Iron (Fe)	ASTM E2371		0.25	0.19	Conforming
Oxygen (O)	ASTM E1409		0.13	0.13	Conforming
Carbon (C)	ASTM E1941		0.08	0.03	Conforming
Nitrogen (N)	ASTM E1409		0.05	< 0.01	Conforming
Hydrogen (H)	ASTM E1447		0.012	0.002	Conforming
Yttrium (Y)	ASTM E2371		0.005	< 0.001	Conforming
Other elements, each	ASTM E2371		0.10	< 0.10	Conforming
Other elements, total	ASTM E2371		0.40	< 0.40	Conforming
Titanium (Ti)	ASTM E2371	Bal	Bal	Bal	Conforming
Chemical analysis laboratory: Luvak Inc. (722 Main Street, P.O. Box 597, Boylston MA, 01505). Report: 0-85825					

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POWDER CHARACTERIZATION							
Description	**Required**	**Measured**	**Status**	**Description**	**Required**	**Measured**	**Status**
Flow rate per ASTM B213				**Particle size distribution per ASTM B214**			
Flow rate (sec/50 g)	Report	30	NA	*Standard ASTM B214 applies to powder sizes 45 microns and higher. The results are for information only.			
Apparent density per ASTM B212				**Size (µm)**	**% By Mass**	**% By Mass**	
App density (g/cm^3)	Report	2.48	NA	>45	Report	4.6	NA
				≤45	Report	95.4	NA
Particle size distribution per ASTM B822 (Coulter® LS13320)							
D10 (µm)	Report	20	NA				
D50 (µm)	Report	34	NA				
D90 (µm)	Report	46	NA				
<15 µm (% by Vol.)	Report	3	NA				
Analyses were done by AP&C at their location and reported results are rounded following ASTM E29.							

We hereby certify that the above values conform to the requirements of Purchase Order 656 .

2018-12-14

Date (yyyy-mm-dd)

Catherine Lavoie

Digitally signed by Catherine Lavoie
Date: 2018-12-14 13:16-05:00

Quality department

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DAY 1
PART 2

1

Stages of Development

Description of the stages of new production from design to qualified product and process

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Main stages

Product design and development

Process design and development

Machine qualification

Product and process validation

Quality control

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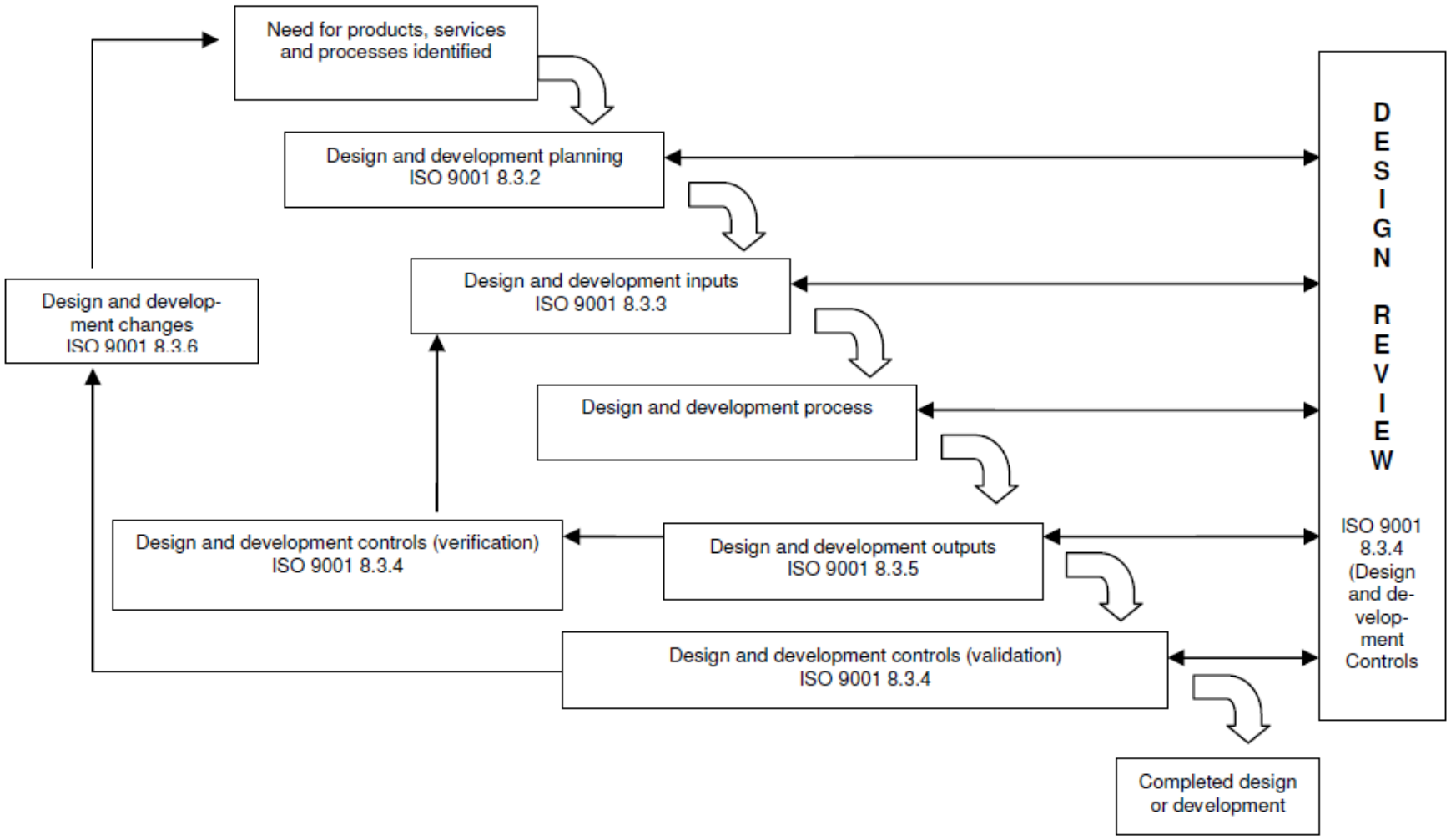

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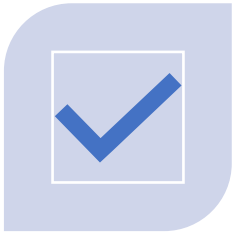
Product Design and Development

Risk analysis at the beginning of the design process is a **new practice** being implemented across manufacturing industry. Historically, engineers would design and then carry out risk analysis which is more costly.

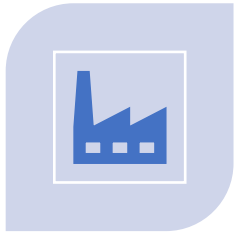
Example: ISO Medical Device 13485

Designed to capture risk at the beginning of the design process.



REQUIREMENTS CAPTURE

PRODUCT DESIGN



REVIEW OF THE DESIGN FOR MANUFACTURE AND ASSEMBLY

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DAY 1
PART 2

IMRAM

Additive Manufacturing Adoption Framework

1

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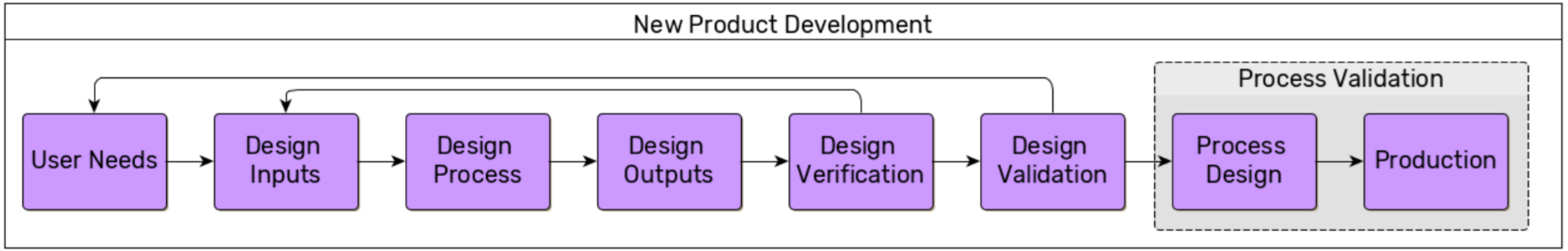
New Product Development Flow



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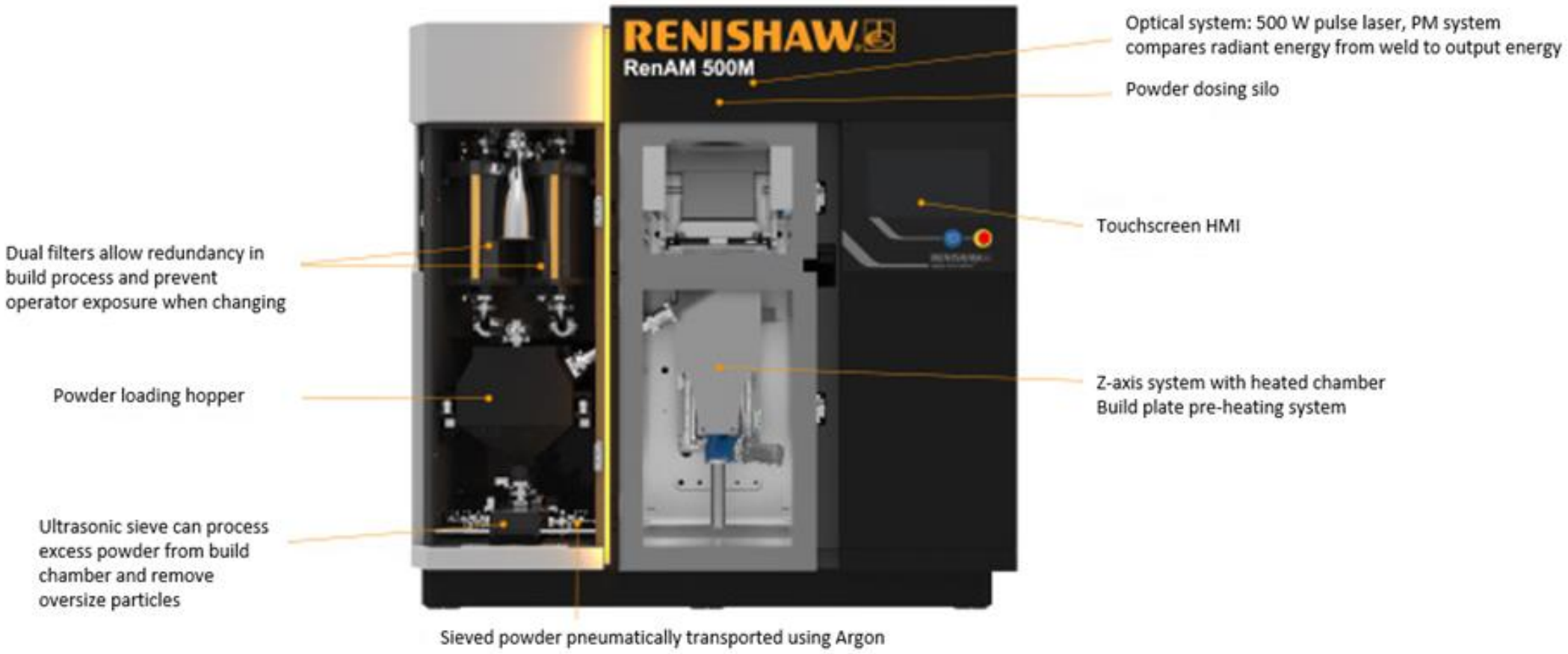

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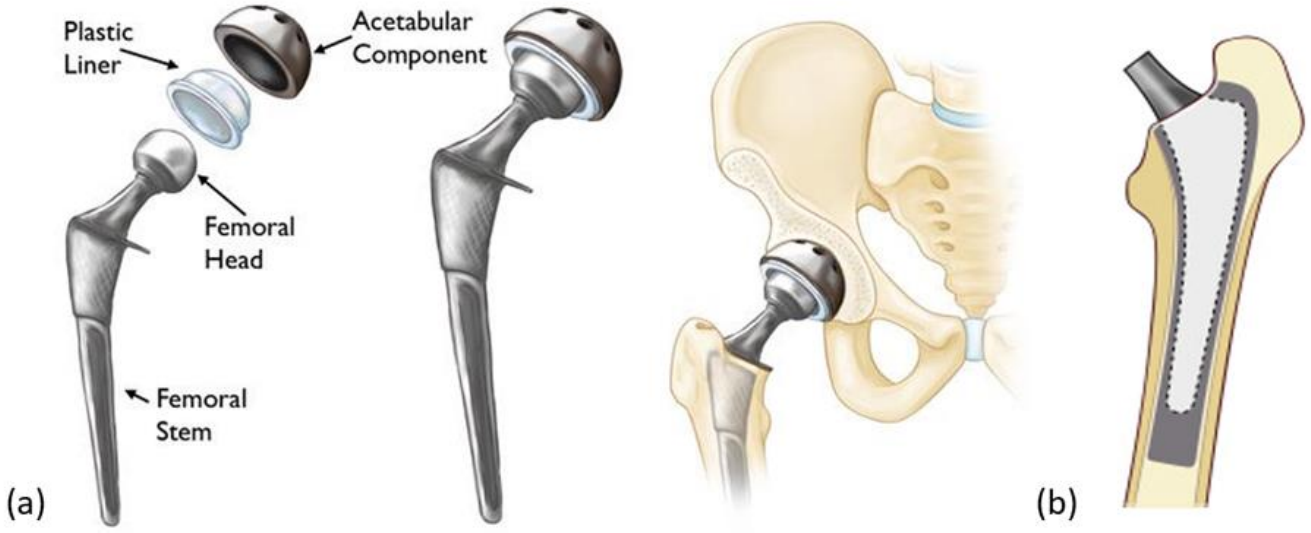
Exemplar II – Hip Stem



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VoX
Voice of the Customer
& the Voice of Business.

If these voices fail to align in agreement, then the product is not viable.

IMR uniquely created what we call the **Voice of Technology** integrated throughout the workflow.

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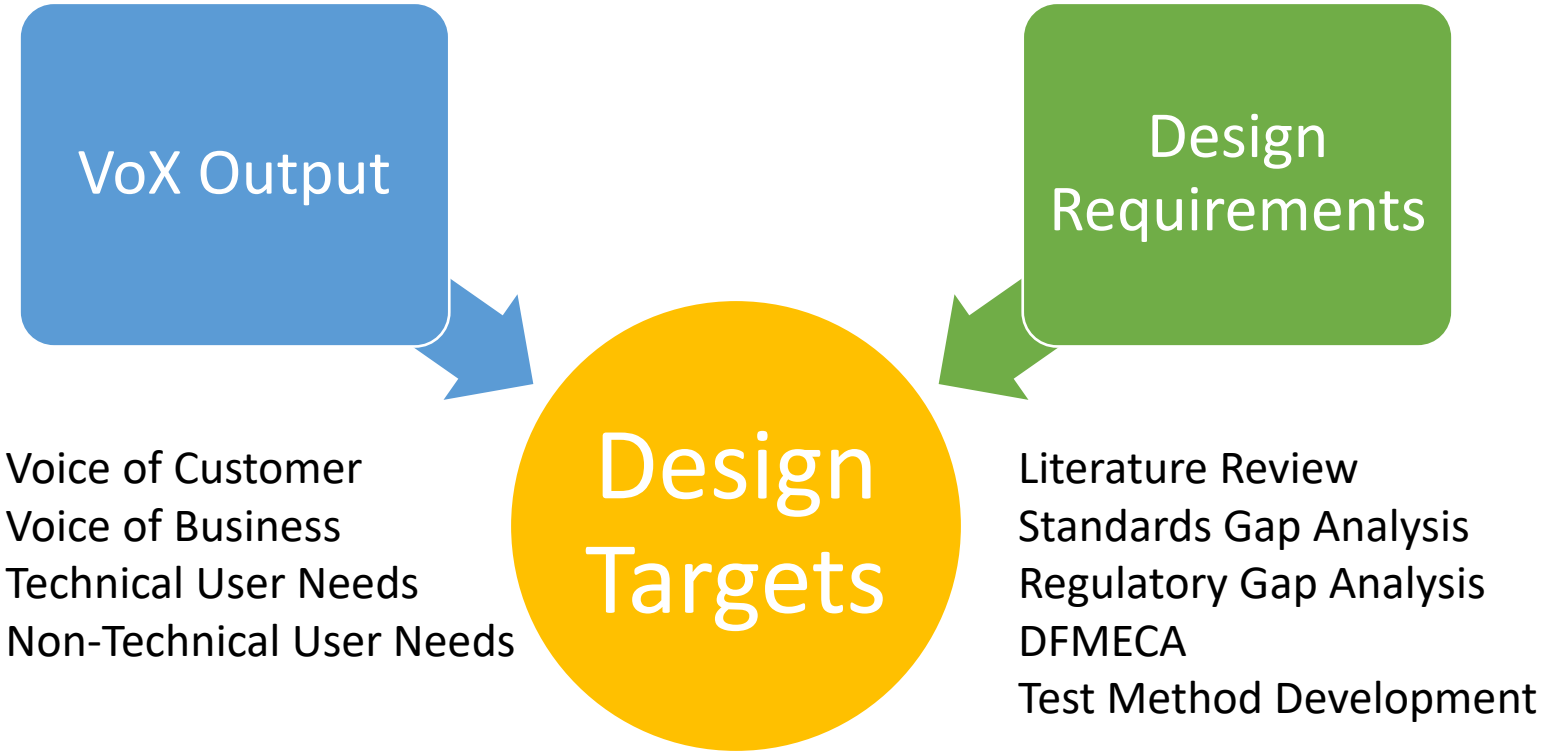
Assessment of VoX Findings



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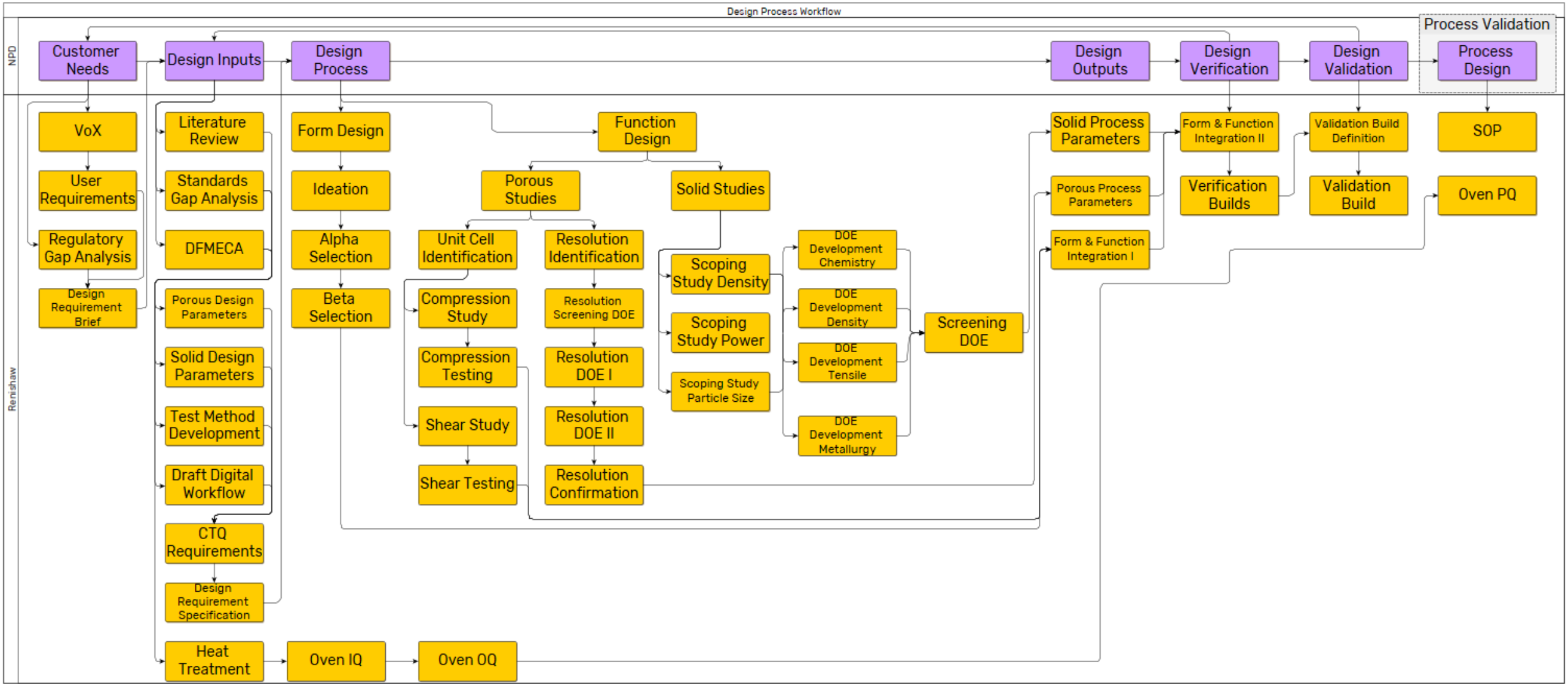

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Design Process –AM Advantages

As part of the AM Design Process a number of key advantages were identified

- **Rapid prototyping** on **production machine**.
- **Agile** Design process
- Rapid **Virtual Iteration**
- **Statistically Driven Design**

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Process Design and Development

Numerous steps

PROCESS CAPABILITY (GEOMETRY AND MATERIAL PROPERTIES)

PROCESS FLOW AND OPERATING WINDOWS

UNDERSTAND LIMITATIONS

UNDERSTAND PROCESS FAILURE MODES

GEOMETRICAL LIMITATIONS

ESTABLISH CONTROL PLAN

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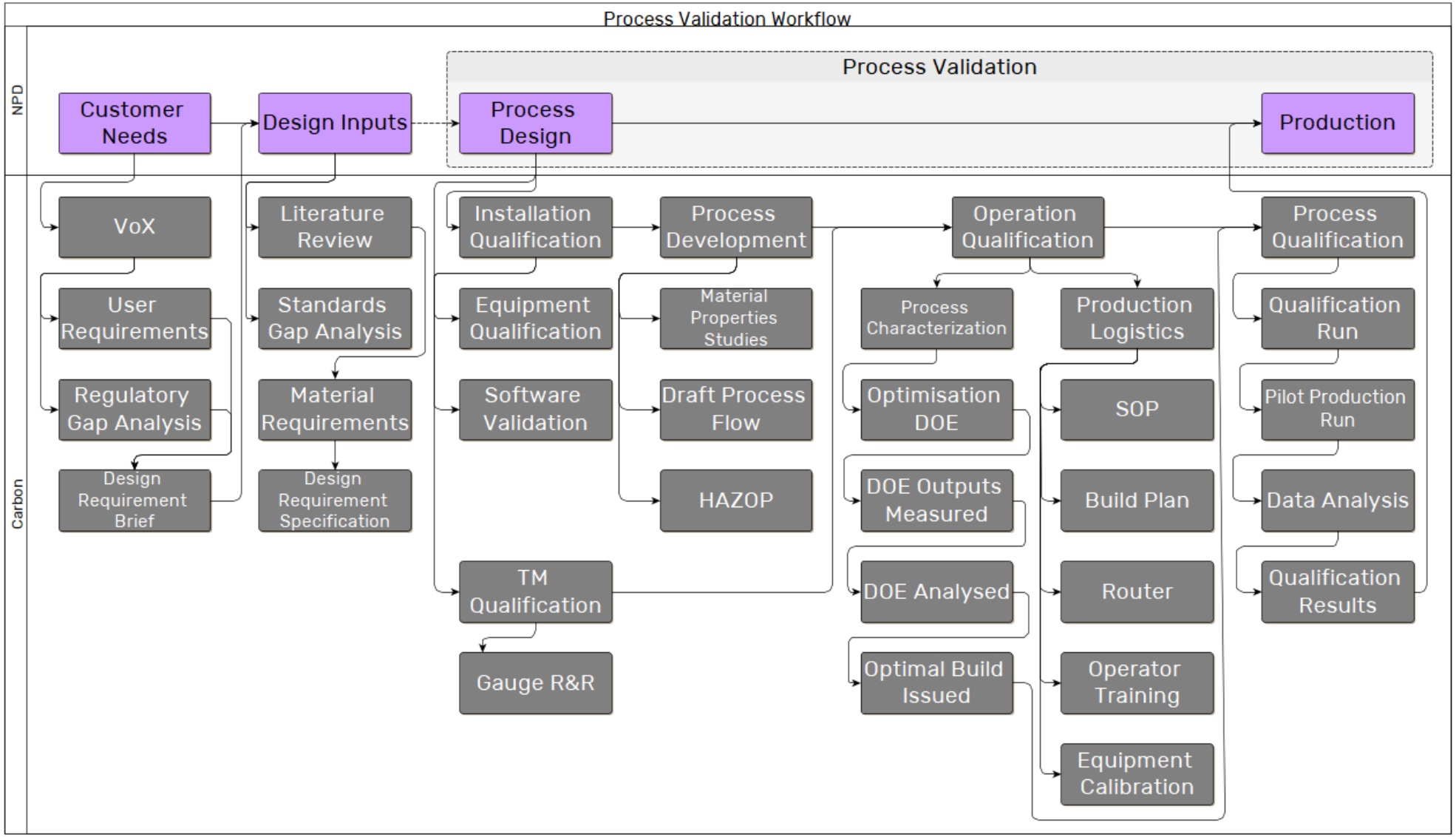

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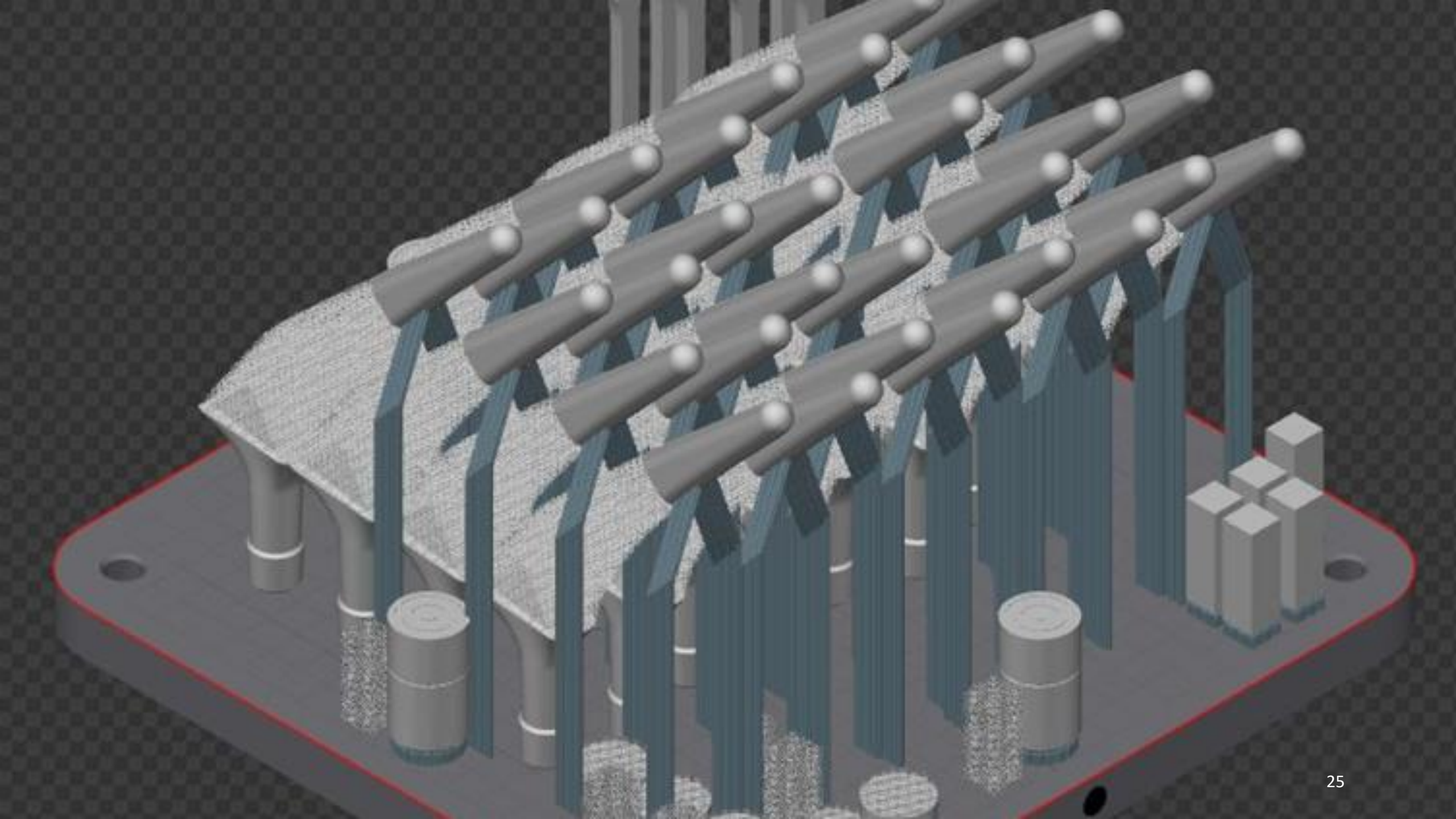
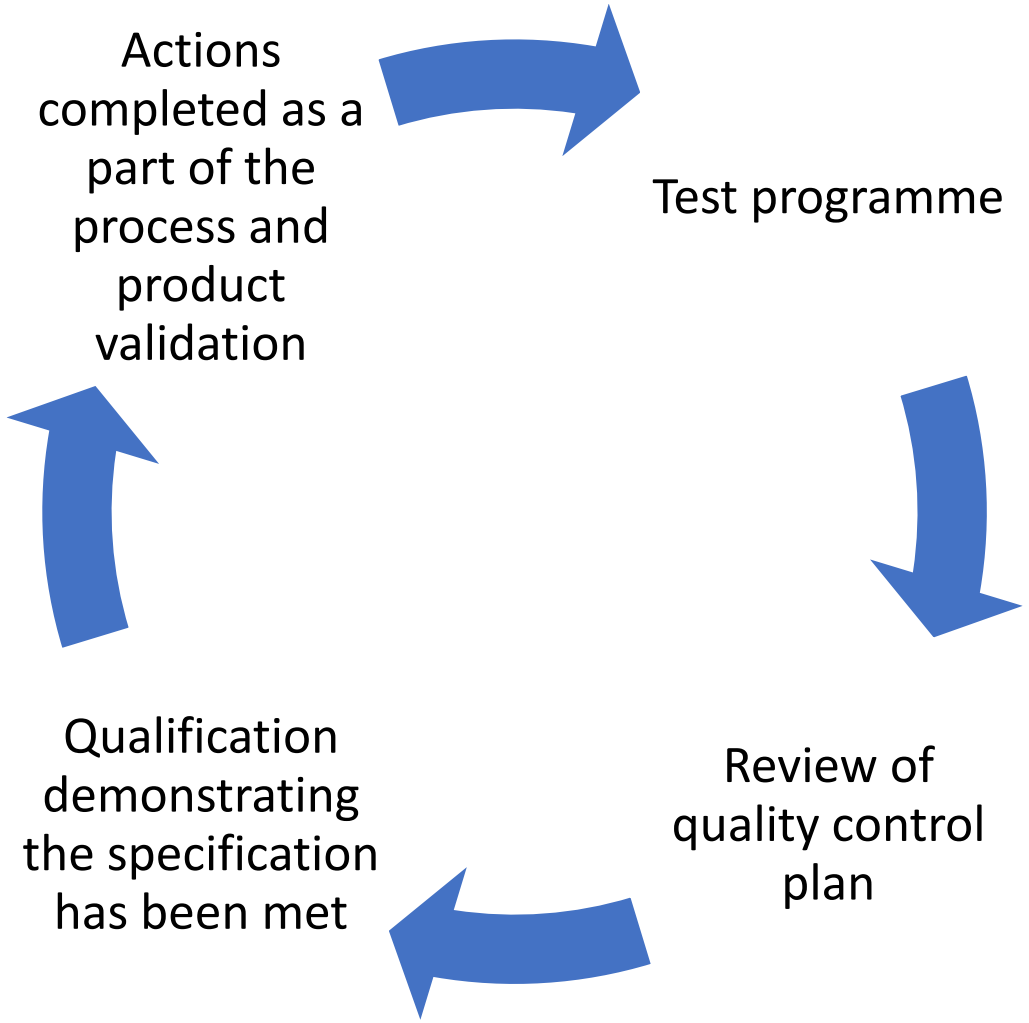
Figure 6: Coupon positions for in-process verification



Product and Process Validation

Test, Review, Qualification, Validation



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Quality Control

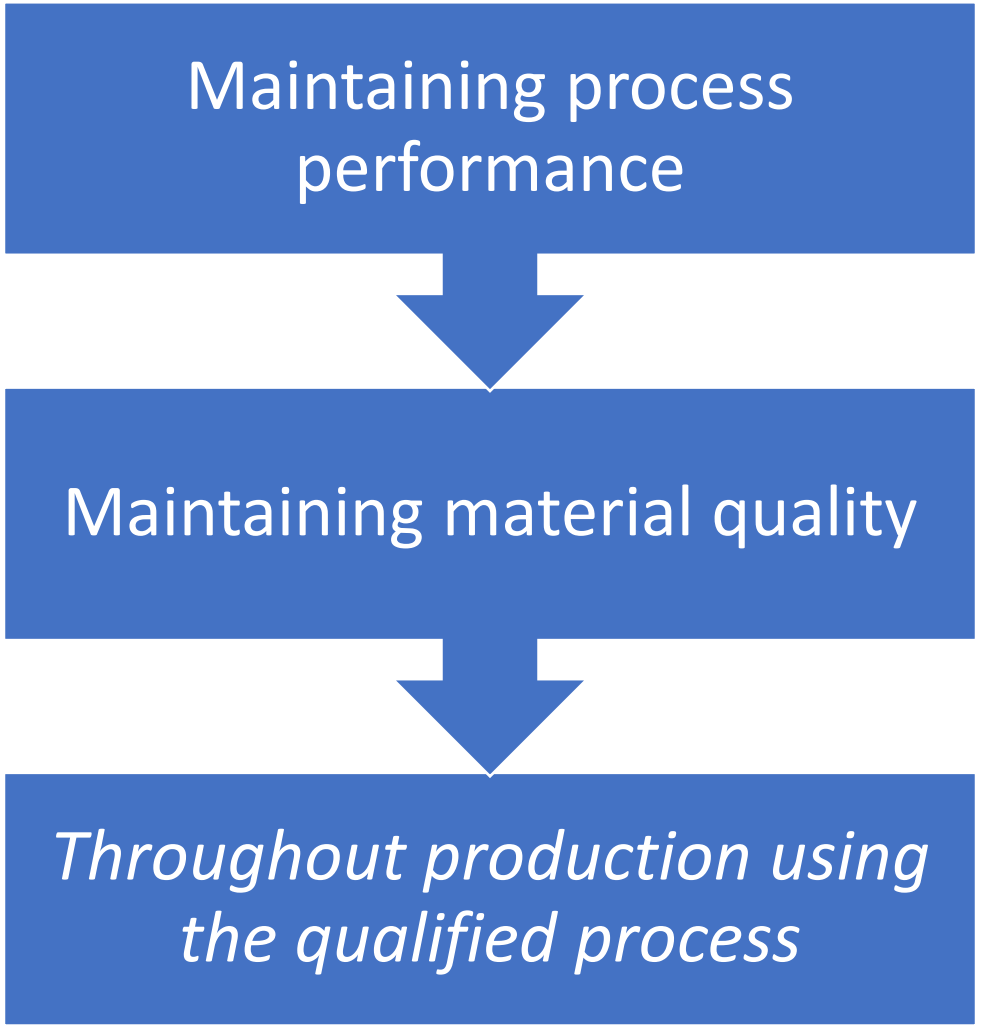
Subcontracting and legal responsibility

Approval Requirements

Production Readiness

Metal Additive Manufacturing

Duty of Care



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THANK YOU!

Any questions?

IRISH
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