FAN 3D

CU 63 – Certification, Qualification & Standardisation

Pedro Catarino

23rd November 2021

Contents

Learning Outcomes

- ✓ Outline certification, qualification and standardisation activities identifying the main differences associated to each one
- ✓ Recognize the standards applicable to additive manufacturing
- ✓ Find the relevant standards to AM applications available in public repository
- ✓ Identify the impact of qualification, certification and standardisation in the AM enabled process chain
- ✓ Identify how CQS can prevent the specific risks and implications related with AM implementation

Additive Manufacturing

Additive Manufacturing; shaping objects by successive addition of material…

New Technology?

A scallop

First modern system: *Stereo Lithography*, patent 1986, first machine sold in 1987

Additive Manufacturing

- **Design complexity**: design changes that would often take months using conventional manufacturing methods can be implemented much faster. AM is a cost-effective technology for producing parts with complex geometries. Designs that would otherwise be impossible to produce with conventional manufacturing can now be produced with AM;

- **Shorter lead times**: as AM requires no tooling, manufactures can reduce the time needed to produce parts, bypassing the time consuming and costly tooling production step;

Additive Manufacturing

- **On-demand production**: since AM can produce physical parts from digital files in a matter of hours, companies can leverage a new model of manufacturing parts on demand;

- **Mass customization**: no tooling constraints means that products can be built to an individual's specification e.g. Invisalign take scan of consumers mouths and produce braces tailored for individuals using AM printers;

- **Light weight**: the ability to print internal strengthening structures allows the maximum strength to weight ratio e.g. the arm for monitors on virgin planes.

Additive Manufacturing

- 1970-s and 80-s: Developments in 3D CAD
- 1980-s; challenges, among others, in the US automotive industry identified the need for augmented prototyping processes
- Several "Rapid Prototyping" (RP) processes developed during the 1980-s and early 90-s, for example:
    - Stereolithography (SLA, Hull, 1986)

Additive Manufacturing

- ❖Selective sintering (SLS, Deckard, 1989)
- ❖Rapid Prototyping": several systems launched through the late 1980s and the early 1990s
- ❖Fabrication of components by layered deposition (Vannon D. Pratt et al. 1991)
- ❖"Apparatus and Method for Creating Three-Dimensional Objects" -Fused deposition modelling (FDM, Crump, 1992)

Additive Manufacturing

- Techniques for Three Dimensional printing (3DP, Emanuel M. Sachs et al. 1993)
- Laminated Object Manufacturing (LOM, Feygin, Sung 1996)
- "Rapid Tooling" (1990's to early 2000's) ; producing tools based on "RP" technology ex. Keltool, Wibatool, early DMLS…
- "Rapid Manufacturing" (late 1990's to mid 2000's): producing end-use parts based on "RP"- technology, -found some applications but did not really take off on an industrial scale

Additive Manufacturing

- Prototyping processes vs. Industrial manufacturing processes
  - ✓A prototyping process includes everything from concept idea to the delivery of the physical prototype. Requirements are ad-hoc and settled by agreement between service provider and customer.
  - ✓An industrial manufacturing process consists of a series of sub-processes, with defined interfaces and specified requirements. Consistency, predictability, traceability and quality control… Predetermined product requirements!
- Producers and customers: purchasing process, roles and responsibilities, communication… - **Need for standardizsation**!

STANDARDISATION

Standardisation

"A standard is a specification of best practice as agreed by consensus among experts"

Standardisation

- Document for voluntary application that has been established by consensus between all interested parties and approved by a recognized body.

- Provides requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose.

- Communicating guidance
  - ✓ "What do you mean by RP, RT, RM, FFF, LF, SFF, ALM, ALF, AF, DDF, DDM, 3DP, (- and others)?"

Standardisation

- Defines test methods and protocols.
- Certifying bodies typically reference publicly available standards in their procedures.
- Documenting technical data.
- Accelerating the adoption of new technologies.

Standardisation

"Mission is to share knowledge, innovation and best practice to help people and organizations make excellence a habit."

(https://www.bsigroup.com/en-GB/)

Standardisation

National level – <u>National Standardisation Bodies</u>

- BSI – United Kingdom
- DIN – Germany
- IPQ – Portugal
- Etc…

Standardisation

Regional level

- **CENELEC**: European Committee for Electrotechnical Standardization is responsible for European standardization in the area of electrical engineering. Together with ETSI (telecommunications) and CEN (other technical areas), it forms the European system for technical standardization

https://www.cencenelec.eu/

Standardisation

Regional level

- **CEN**: The European Committee for Standardisation is a public standards organization whose mission is to foster the economy of the European Single Market and the wider European continent in global trading. Develops European Standards (EN).

https://www.cencenelec.eu/

For AM -> CEN TC/438

Standardisation

International level

- **IEC**: The International Electrotechnical Commission is an international standards organization] that prepares and publishes international standards for all electrical, electronic and related technologies.

https://www.iec.ch/homepage

Standardisation

International level

- **ASTM International:** American Society for Testing and Materials, is an international standards organization that develops and publishes voluntary consensus technical standards for a wide range of materials, products, systems, and services.

https://www.astm.org/

Standardisation

International level

- **ISO:** The International Organization for Standardization is an international standard-setting body composed of representatives from various national standards organizations and develops and publishes worldwide technical, industrial and commercial standards.

https://www.iso.org/home.html

Standardisation

➢**ASTM International, Committee F42**

- Established 2009, -coined & defined "Additive Manufacturing"
- **Scope:** "The promotion of knowledge, stimulation of research and implementation of technology through the development of standards for additive manufacturing technologies."
- Membership is based on representation of different stakeholders: companies, universities, research organisations etc.
  - 1 vote/organisation

Standardisation

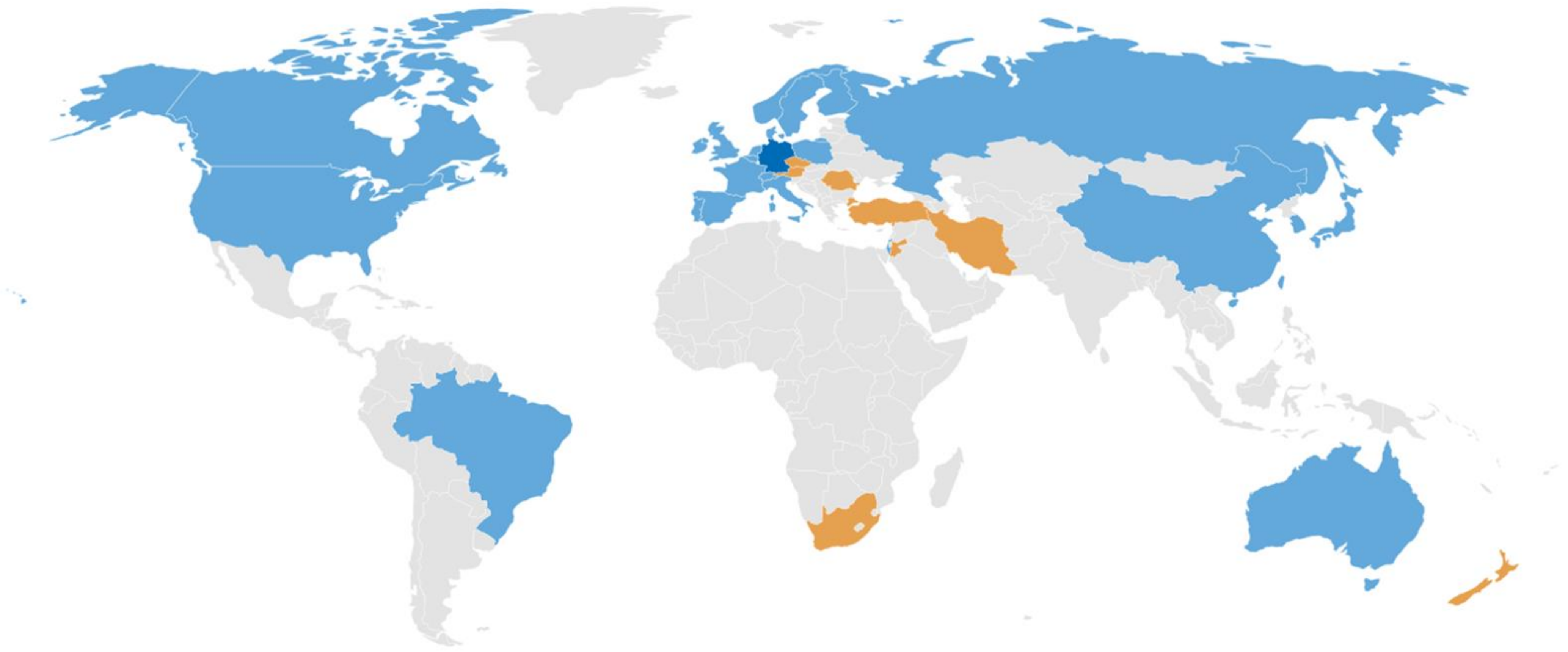
➢ISO Technical Committee 261 (ISO/TC261)

- Established 2011, after an initiative from DIN, based on VDI Guidelines on "Rapid Technologies"

- **Scope:** "Standardization in the field of Additive Manufacturing (AM) concerning their processes, terms and definitions, process chains (Hard- and Software), test procedures, quality parameters, supply agreements and all kind of fundamentalsmanufacturing technologies.“

- Membership is based on representation of different national standardization organization. Each member organization may nominate experts for different workgroups.
    - 1 vote/organisation

Standardisation



This map is designed to visually demonstrate the geographic distribution of our Members. The boundaries shown do not imply an official endorsement or acceptance by ISO.

Standardisation

Standards are needed, but we don't necessarily need several competing standards…

ISO & ASTM have signed a Partnership Standards Development Organization (PSDO) agreement

- Fast tracking the adoption process of an ASTM International standard as an ISO FDIS (Final Draft International Standard)
- Formal adoption of a published ISO standard by ASTM International
- Maintenance of published standards
- Publication, copyright and commercial arrangements

James Thomas, ASTM President, and Rob Steele, ISO Secretary-General

Standardisation

Standards are needed, but we don't necessarily need several competing standards…

Guiding principles:

- One set of AM standards – to be used all over the world
- Common roadmap and organizational structure for AM standards
- Use and build upon existing standards, modified for AM when necessary
- Emphasis on joint standards development

James Thomas, ASTM President, and Rob Steele, ISO Secretary-General

Standardisation

- What are we actually working on?
  - Name? The least common denominator…
  - Definition: what is the actual *AM-process*, and what is a the AM enabled *production chain*?
  - Single-step and multi-step processes

- Many different processes, with trademarked names: categorization..!

- Identification of process categories:
  - Identification of common denominators based on <u>process architecture</u>
  - Naming of process categories

Standardisation

Understanding AM - Definition by ISO/ASTM 52900:

3.1.2
additive manufacturing, noun
AM
process of joining materials to make *parts* (3.9.1) from 3D model data, usually *layer* (3.3.7) upon layer, as opposed to subtractive manufacturing and formative manufacturing methodologies

Note 1 to entry: Historical terms include: additive fabrication, additive processes, additive techniques, additive layer manufacturing, layer manufacturing, solid freeform fabrication and freeform fabrication.

- *AM is enabled by the creation and communication of a 3D model data file*
  - *The 3D model is, in practice, a specification for the parts made by an AM process*
- *An AM process is characterized by how the material is added:*
  - *Mechanism for delivering the feedstock material*
  - *Mechanism for joining the feedstock – Subject to the laws of physics and chemistry!*

Standardisation

By definition: "process of joining materials to make parts from 3D model data…"

- The beginning, defined by: "….from 3D model data…."
- The end, defined by: "….to make parts…"

The AM process starts by the 3D model file and ends when all the material needed to fulfil the specification of this model has been joined to a part

Standardisation

- In the beginning: Many different processes, with common traits, but different trademarked names
- Categorization based on common process architecture
- 7 Process categories identified (so far):
    - ❖ Binder jetting (BJT)
    - ❖ Directed energy deposition (DED)
    - ❖ Material extrusion (MEX)
    - ❖ Material jetting (MJT)
    - ❖ Powder bed fusion (PBF)
    - ❖ Sheet lamination (SHL)
    - ❖ Vat photopolymerization (VPP)

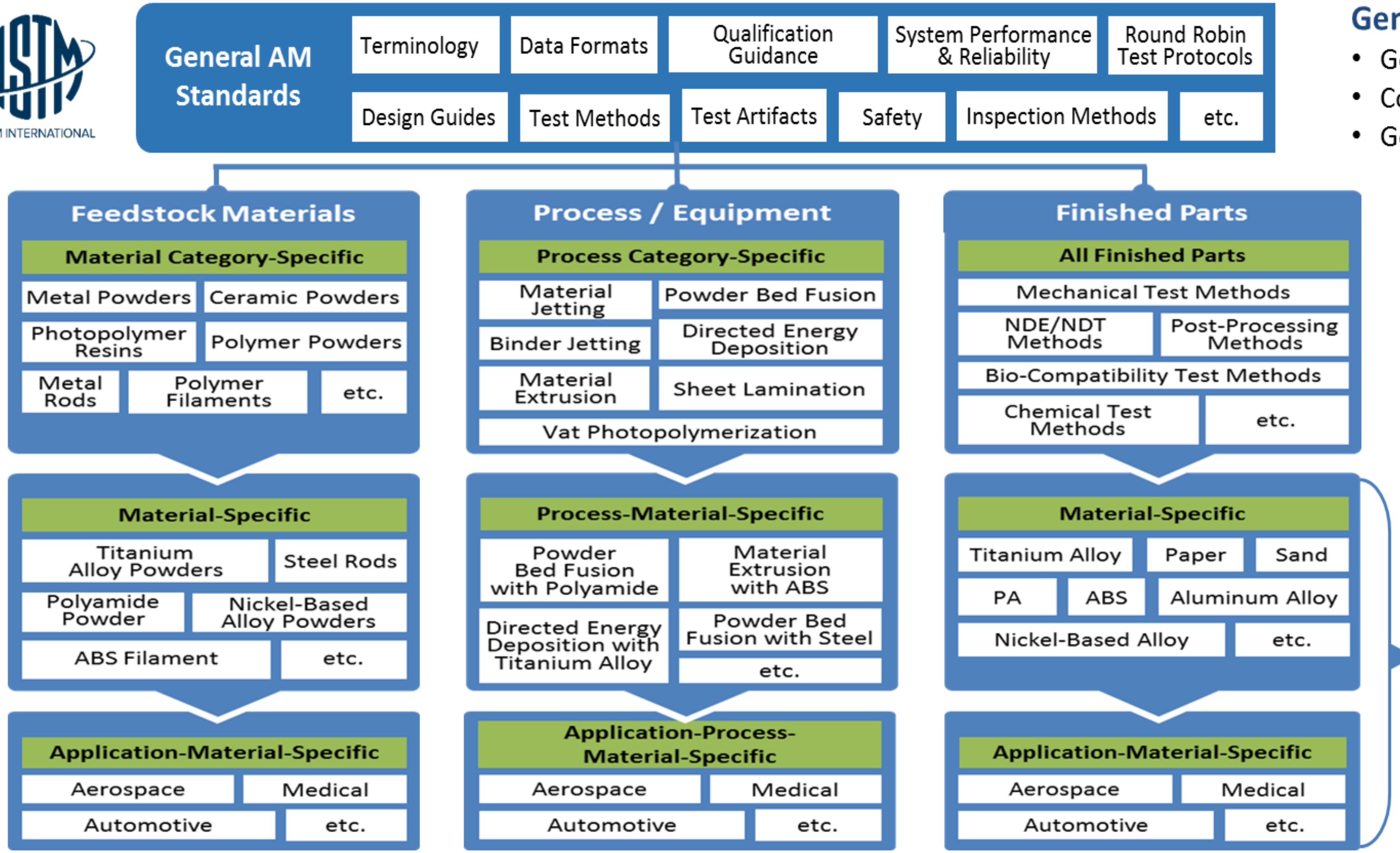
→ **ISO 17296-2**

Standardisation

<u>Very basic:</u>

- All standards development is based on contribution from members
  - Members are stakeholders and base their contribution on an interest in developing the standards
  - No funding or compensation provided from the Standards Developing Organization (SDO)
  - SDO's have all the IPR
- Consensus based!
- ASTM: experts nominated directly by stakeholder (Company, University, Professional organization, etc.)
  - Type of membership depend on the nature of the stakeholder's interest
- ISO & CEN experts nominated national SDO committees, -which is based on stakeholder memberships

Standardisation



General Top-Level AM Standards

- General concepts
- Common requirements
- Generally applicable

Category AM Standards

Specific to material category or process category

Specialized AM Standards

Specific to material, process, or application

Standardisation

Sub-Committees

- F42.01 Test Methods
- F42.04 Design
- F42.05 Materials and Processes
  - F42.05.01 Metals
  - F42.05.02 Polymers
  - F42.05.05 Ceramics
- F42.06 Environment, Health, and Safety
- F42.07 Applications*
- F42.08 Data
- F42.91 Terminology

Workgroups

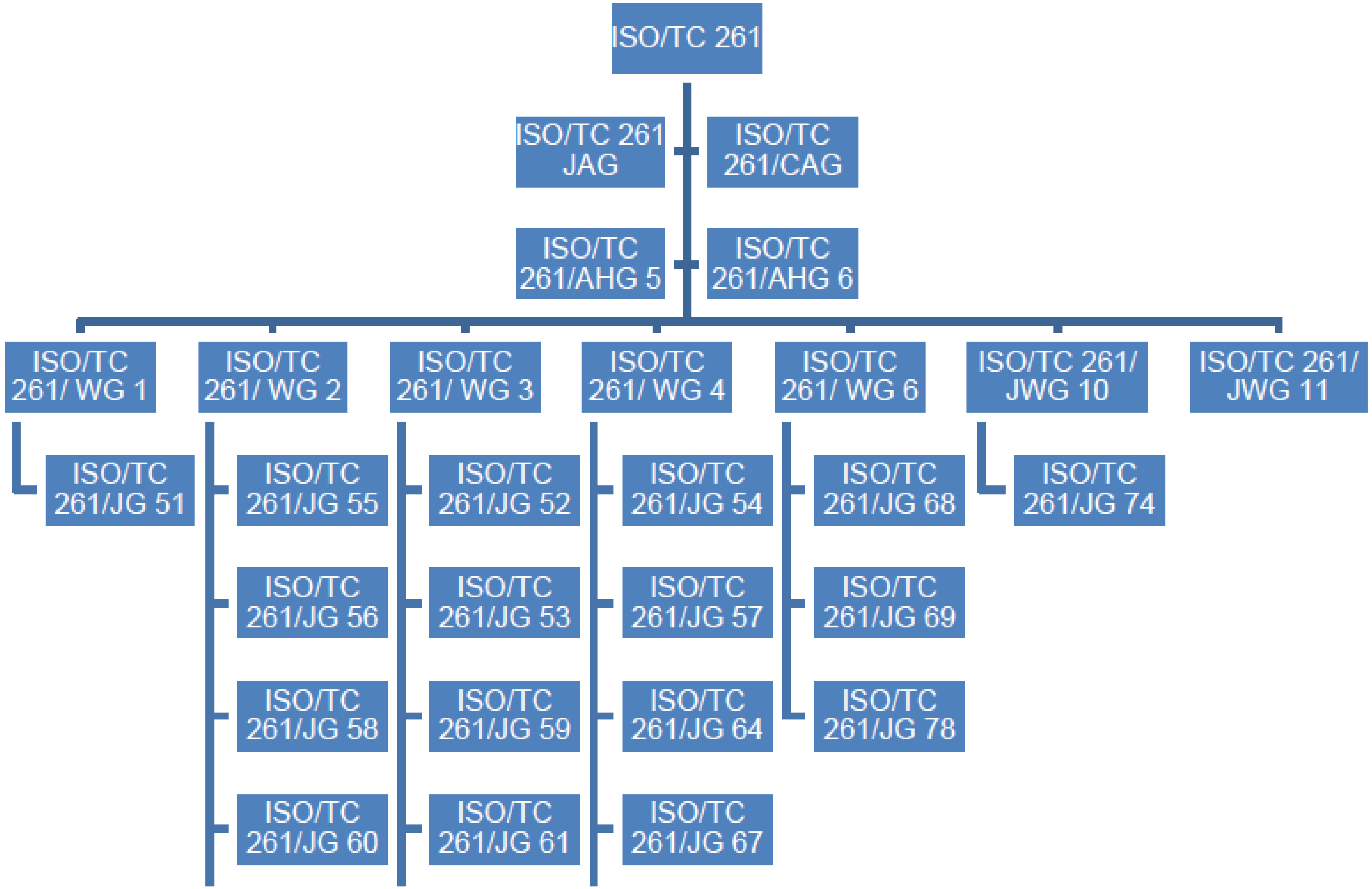
- ISO/TC 261/WG 01 "Terminology"
- ISO/TC 261/WG 02 "Processes, systems and materials"
- ISO/TC 261/WG 03 "Test methods and quality specifications"
- ISO/TC 261/WG 04 "Data and Design"
- ISO/TC 261/WG 06 "Environment, health and safety"
- JWG 10 "Joint ISO/TC 261 - ISO/TC 44/SC 14 WG; Additive manufacturing in aerospace applications
- JWG 11 "Joint ISO/TC 261 - ISO/TC 61/SC 9 WG; Additive manufacturing for plastics"
- ISO/TC 150/JWG 1: Joint ISO/TC 150 - ISO/TC 261 WG: Additive manufacturing in surgical implant applications

Standardisation

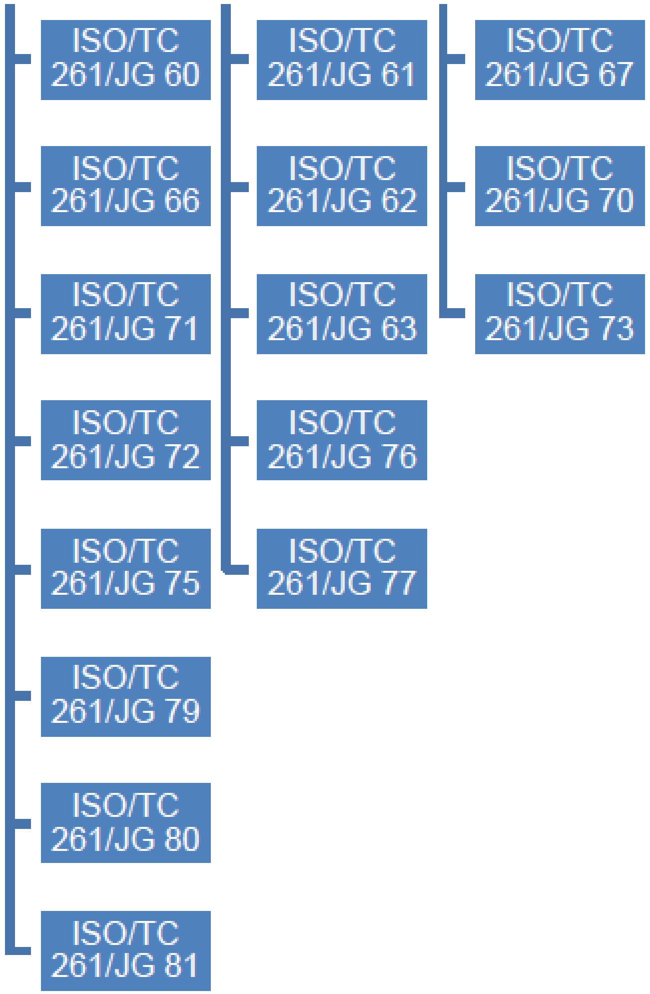
"*Bridging the gap between AM standards and existing product specifications*"

- F42.07.01: Aviation
- F42.07.02:Spaceflight
- F42.07.03: Medical/Biological
- F42.07.04: Transportation/Heavy machinery
- F42.07.05: Maritime
- F42.07.06: Electronics
- F42.07.07: Construction
- F42.07.08: Oil & Gas
- F42.07.09: Consumer
- F42.07.10: Energy

Standardisation



Standardisation



Standardisation

- Currently 30 active ISO/ASTM JGs
- Working on 34 different standards
- 17 joint ISO/ASTM standards on AM published
- 3 ISO/TC261 standards on AM published
- 16 ASTM F42 standards on AM published

For more information, please see:

- https://www.iso.org/committee/629086.html
- https://www.astm.org/COMMIT/SUBCOMMIT/F42.htm

Standardisation

The documents produced by Technical Committees are:

- International (ISO) and European Standards (EN)
- Technical Specifications (TS)
- Technical Reports (TR)
- CEN Workshop Agreements (CWA)
- Publicly Available Specifications (PAS)

Standardisation

- **Technical Specifications**: document for which there is the future possibility of agreement on a Standard, but for which at present:
  — the required support for approval as a Standard cannot be obtained;
  — there is doubt on whether consensus has been achieved;
  — the subject matter is still under technical development; or
  — there is another reason precluding immediate publication as a Standard.

  A Technical Specification is not allowed to conflict with an existing International Standard

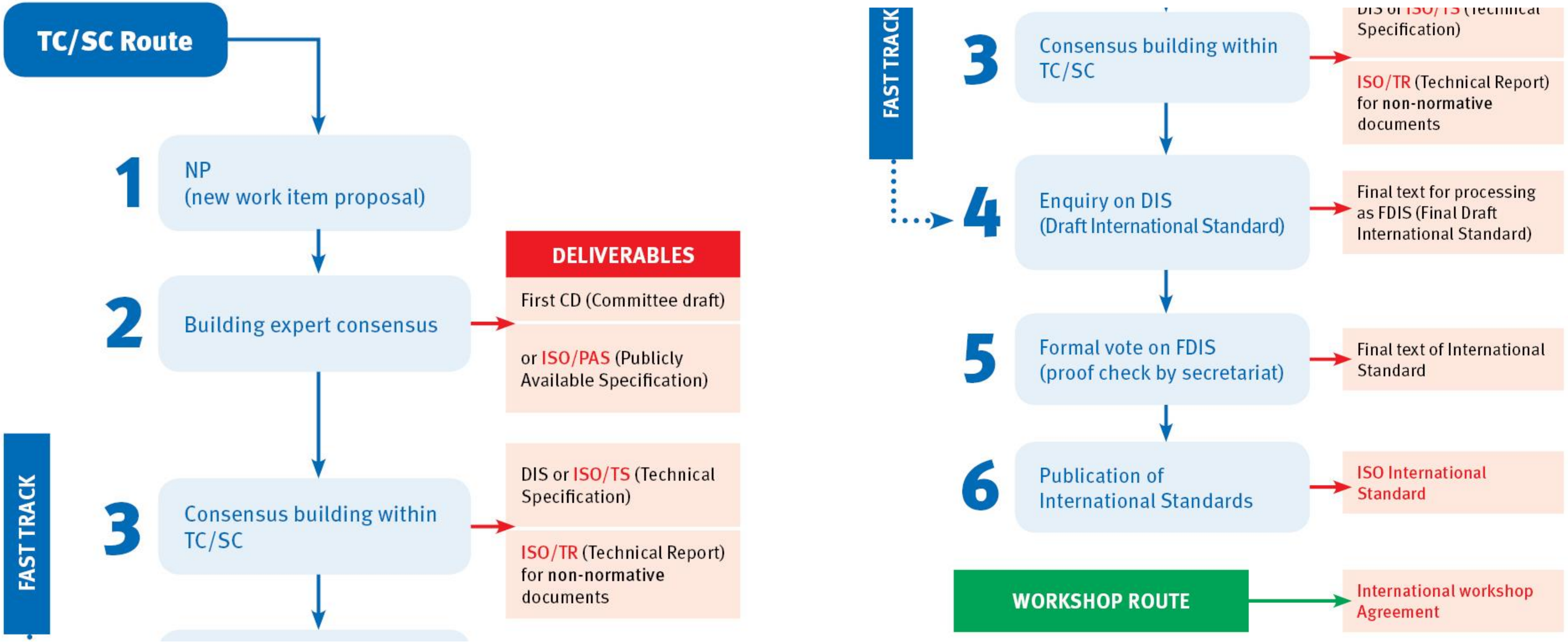
- **Technical Report**: a document containing informative material not suitable to be published as a Standard or a Technical Specification (TS). A TR can include, for example, data obtained from a survey carried out among the national members, data on work in other organizations or data on the state of the art in relation to national Standards on a particular subject.

Standardisation

- **PAS**: a fast-track standardization document. It defines good practice for a product, service or process. It’s a powerful way to establish the integrity of an innovation or approach.

- **CEN Workshop Agreement**: is a reference document from the European Committee for Standardization (CEN). It is, by definition, not an official standard from the member organizations.

Standardisation



Standardisation

- Draft for review by both organizations
- Parallel ASTM and ISO ballots
  - ISO/TC 261: "Draft International Standard" (DIS) ballot; 3-month balloting cycle
    - Approval requires more than 66.67% Affirmative, and no more than 25% Negative
  - An FDIS ballot may be needed…
    - Yes/No vote: 66.67% Affirmative, and no more than 25% Negative required for approval
  - ASTM F42: Final balloting; 30-days balloting cycle
    - Approval requires more than 60% returned ballots, <u>No Negatives,</u> Affirmative/Abstain only
- Editorial changes are allowed, comments resulting from the ASTM balloting can be submitted into the ISO balloting process

Standardisation

Search and find…!

- ASTM standards: https://www.astm.org/search/fullsite-search.html?query=compass&
  - The ASTM International Compass: Search keywords; +"additive manufacturing"
- ISO standards: https://www.iso.org/home.html ,
  - ISO search: https://www.iso.org/search.html?q=&hPP=10&idx=all_en&p=0
  - Search keywords; "additive manufacturing"
- CEN standards: https://standards.cen.eu/dyn/www/f?p=CENWEB:105::RESET::::
  - Search title/scope, select Committee "CEN/TC 438"
- Terms and Definitions: https://www.iso.org/obp/ui/#home
  - ISO online browsing platform: Access the most up to date content in ISO standards, graphical symbols, codes or terms and definitions.
  - For AM terms and definitions: search for: "52900“

Standardisation

International standards development

- Development of AM standards is a **key element** in establishing AM as a part of the industrial manufacturing system and provide an intellectual infrastructure to the market.
- **International collaboration** between ASTM, ISO and CEN is formally established and is growing
  - One set of standards used all over the world!
  - Common roadmap and organizational structure for AM standards
    - Use and build upon existing standards, modified for AM when necessary
  - Joint working groups are in progress
- Several standards, both common and by the individual organizations, have been published and **more are on the way**

Standardisation

We are just in the beginning of exploring the many possibilities of AM technology

Knowledge is critical; This is a learning process for all of us

Misdirected expectations leads to disappointments

No one benefits from competing standards.

Please join and take part in the ongoing efforts,

through ASTM F42, ISO/TC261 and your national standardization organizations!

Let's work together and get this right!

QUALIFICATION

Qualification

Different types of qualification existing:

- Qualification of Equipment
- Qualification of Procedures and Specifications
- Qualification of Feedstock
- Qualification of Personnel

Qualification

[ISO/ASTM TS 52930:2021 -]Additive manufacturing — Qualification principles — Installation, operation and performance (IQ/OQ/PQ) of PBF-LB equipment

Additive manufacturing — Qualification principles — Installation, operation and performance (IQ/OQ/PQ) of PBF-LB equipment

1 Scope

This document addresses installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ) issues directly related to the additive manufacturing system that has a direct influence on the consolidation of material. The first three elements of process validation, process mapping, risk assessment, and validation planning, are necessary pre-conditions to machine qualification, however, they are outside the scope of this document.

This document covers issues directly related to the AM equipment and does not cover feedstock qualification or post processing beyond powder removal.

Physical facility, personnel, process and material issues are only included to the extent necessary to support machine qualification.

Qualification

ISO 15614-1 - Specification and qualification of welding procedures for metallic materials — Welding procedure test - Arc and gas welding of steels and arc welding of nickel and nickel alloys

1 Scope

This European Standard is part of a series of standards, details of this series are given in prEN ISO 15607, annex A.

This standard specifies how a preliminary welding procedure specification is qualified by welding procedure tests.

This standard defines the conditions for the execution of welding procedure tests and the range of qualification for welding procedures for all practical welding operations within the range of variables listed in clause 8.

Tests shall be carried out in accordance with this standard. Additional tests may be required by application standards.

This standard applies to the arc and gas welding of steels in all product forms and the arc welding of nickel and nickel alloys in all product forms

Arc and gas welding are covered by the following processes in accordance with EN ISO 4063:

111 - manual metal arc welding (metal-arc welding with covered electrode);

114 - self-shielded tubular-cored arc welding;

12 - submerged arc welding;

Qualification

ISO/ASTM DIS 52924 - Additive manufacturing of polymers — Feedstock materials — Qualification of materials for laser-based powder bed fusion of parts

Additive manufacturing — Qualification principles — Classification of part properties for additive manufacturing of polymer parts

1 Scope

This document establishes the required or the achievable classes of part properties for additive manufactured polymer parts in order to get a common understanding on part quality. It is aimed at providers of manufacturing services for polymer parts who use additive manufacturing machines and at the customers for these services. Designers of parts as well as buyers and providers of manufacturing services can specify, in a traceable manner, the required or the achievable level of part properties with the aid of this standard.

This document applies to parts that have been manufactured from a thermoplastic polymer by means of powder bed fusion with laser for polymers (PBF-LB/P), alternatively named laser sintering (LS) or material extrusion (MEX). Its applicability to other processes for polymers shall be checked in the specific case.

NOTE Laser sintering is also known as *selective laser sintering* (SLS®).

NOTE The process called *material extrusion* (MEX) in ISO/ASTM 52900 is also known as *fused layer modelling* (FLM), *fused layer manufacturing* or *fused deposition modelling* (FDM) or *fused filament fabrication* (FFF).

The classification of part properties apply to parts that have not been post-processed after unpacking from the build space and after removing possible support structures.

Qualification

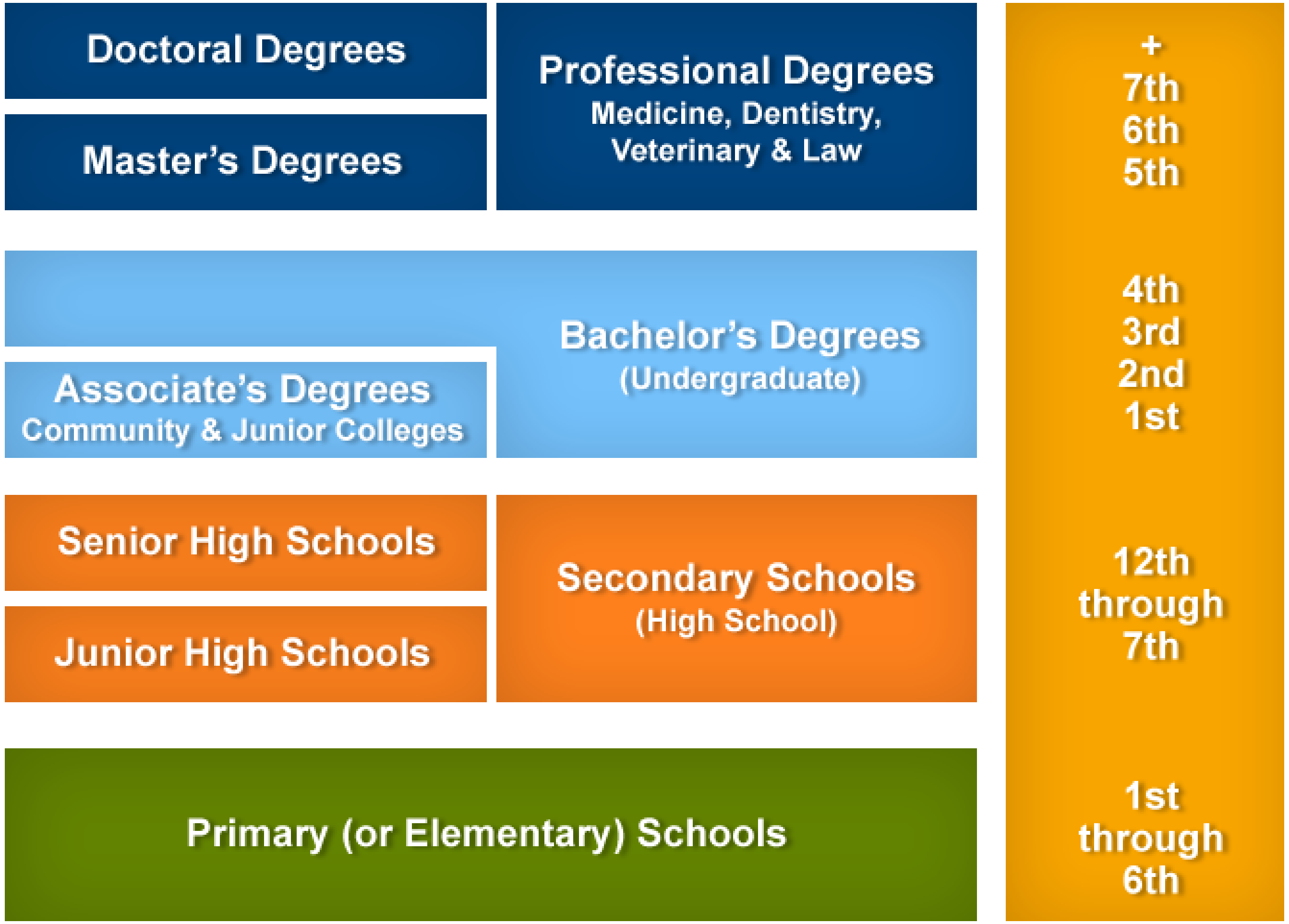
“Qualifications are useful because they make skills visible. It is confidently assumed that the holder of a school-leaving certificate can read and understand instructions, and make calculations, and that those with university degrees can do much more.”

by Simon Field
Senior Analyst, OECD Directorate for Education and Skills

Qualification

National level

- Preschool
- Elementary School
- Middle School
- High School
- University

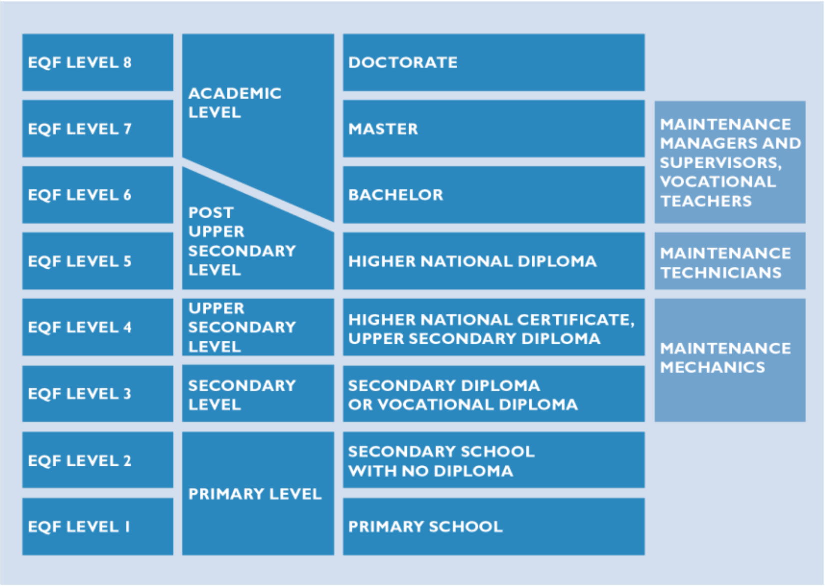


Qualification

➢European Qualification Framework

The [EQF] is a framework for all types of qualifications (8 levels) that serves as a translation tool between different national qualifications frameworks. This framework helps improve transparency, comparability and portability of people's qualifications and makes it possible to compare qualifications from different countries and institutions.

EQF – 10 years of European Qualifications Framework - YouTube



Qualification

➢International Standard Classification of Education (ISCED)

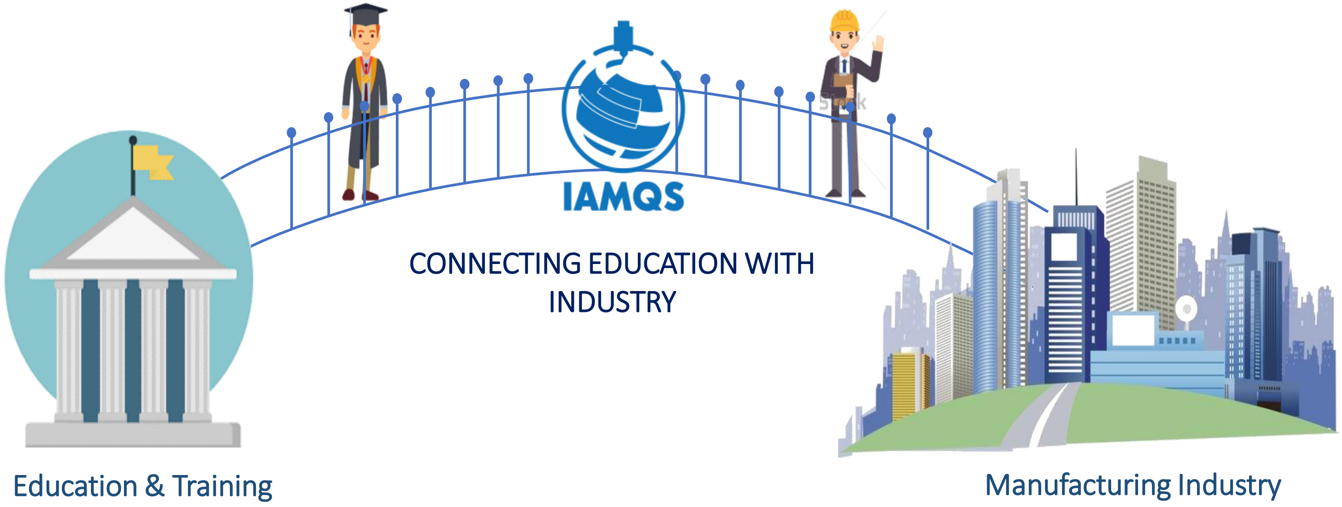
The International Standard Classification of Education (ISCED) is a statistical framework for organizing information on education maintained by the United Nations Educational, Scientific and Cultural Organization (UNESCO).

The UNESCO works closely with Member States and its data collection partners (such as OECD and Eurostat) to map education systems and collect data according to the ISCED classification. National ISCED mappings are published on our page devoted to ISCED mappings.

International Standard Classification of Education (ISCED) | UNESCO UIS

Qualification

➢International AM Qualification System (IAMQS)



Qualification

IAMQS GUIDELINES

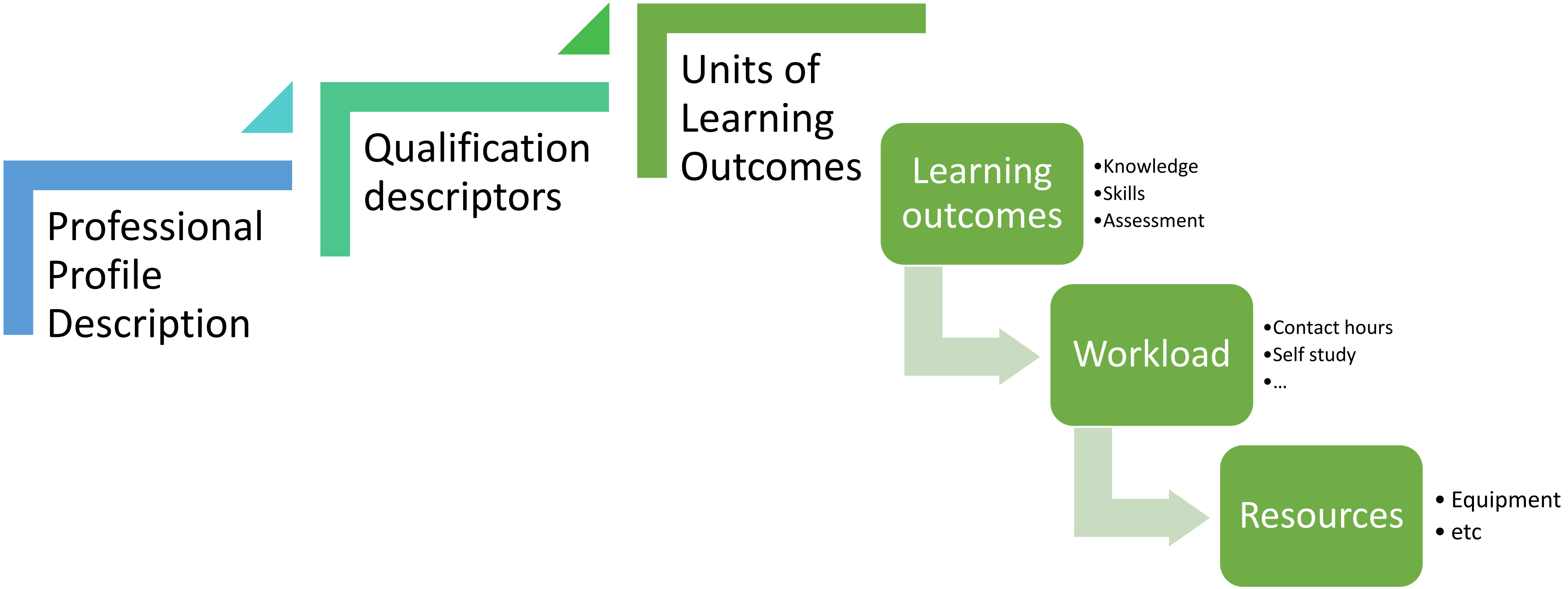
Qualification Guideline

- Description of Professional Profile
- Routes to Qualification
- Access conditions
- Qualification overview – Mandatory & Optional Competence Units

Competence Units Guidelines

- Education and Training – Learning Outcomes
- Detailed knowledge Competence Units
- Examination procedures
- Written, oral and practical examination

Qualification



Qualification

Professional Profile

PBF-LB Process Engineers are the professionals with the specific knowledge, skills, autonomy and responsibility to implement PBF-LB process in the manufacturing chain assuring the efficient production and post-processing of additively manufactured parts. His/her's main tasks are to:

- Evaluate manufacturing suitability for customers' requests defining which processes are fit for the request, based on the application, material, design and cost of the part.
- Apply a wide variety of engineering techniques, contributing to projects in a teaming environment and compare, investigate, transfer, and adapt procedures, techniques, or methods to new applications.
- Develop and execute PBF-LB plans including validation of design, implementation, pre and post processing operations, assurance of parts conformity and identification of the causes and the corrective actions of technical production problems;
- Coordinate the tasks distribution between the operators according to the workplan as well as manage the link between them and the management-

COMPETENCE UNITS	E/IE PBF-LB	
	Recommended Contact Hours*	Expected Workload**
CU 00: Additive manufacturing Process Overview	7	14
CU 01: DED-Arc Process	42	84
CU 08: DED-LB Process	35	70
CU 15: PBF-LB Process	35	70
CU 25: Post Processing	14	28
CU 34: Process selection	28	56
CU 35: Metal AM integration	21	42
CU 36: Coordination activities	7	14
CU 43: Production of PBF-LB parts	21	42
CU 44: Conformity of PBF-LB parts	35	70
CU 45: Conformity of facilities featuring PBF-LB	14	28
TOTAL	259	518
Optional CUs		
CU 26: Introduction to materials	14	28
TOTAL	273	546
Materials CUs* **		
CU 27: AM with steels feedstock (excluding Stainless Steel)	21	42
CU 28: AM with Stainless Steel feedstock	14	28
CU 29: AM with Aluminium feedstock	7	14
CU 30: AM with Nickel feedstock	7	14
CU 31: AM with Titanium feedstock	14	28
CU 32: AM with Tungsten feedstock	3,5	7
CU 33: Biomedical metallic materials	7	14

Qualification

Competence Unit 00: Additive Manufacturing Processes Overview

CU 00: Additive Manufacturing Processes Overview	CONTACT HOURS
SUBJECT TITLE	
Directed energy deposition	1
Powder bed fusion	1
Vat photopolymerization	1
Material jetting	1
Binder jetting	1
Material extrusion	1
Sheet lamination	1
Total	7
WORKLOAD	14

Contact hours

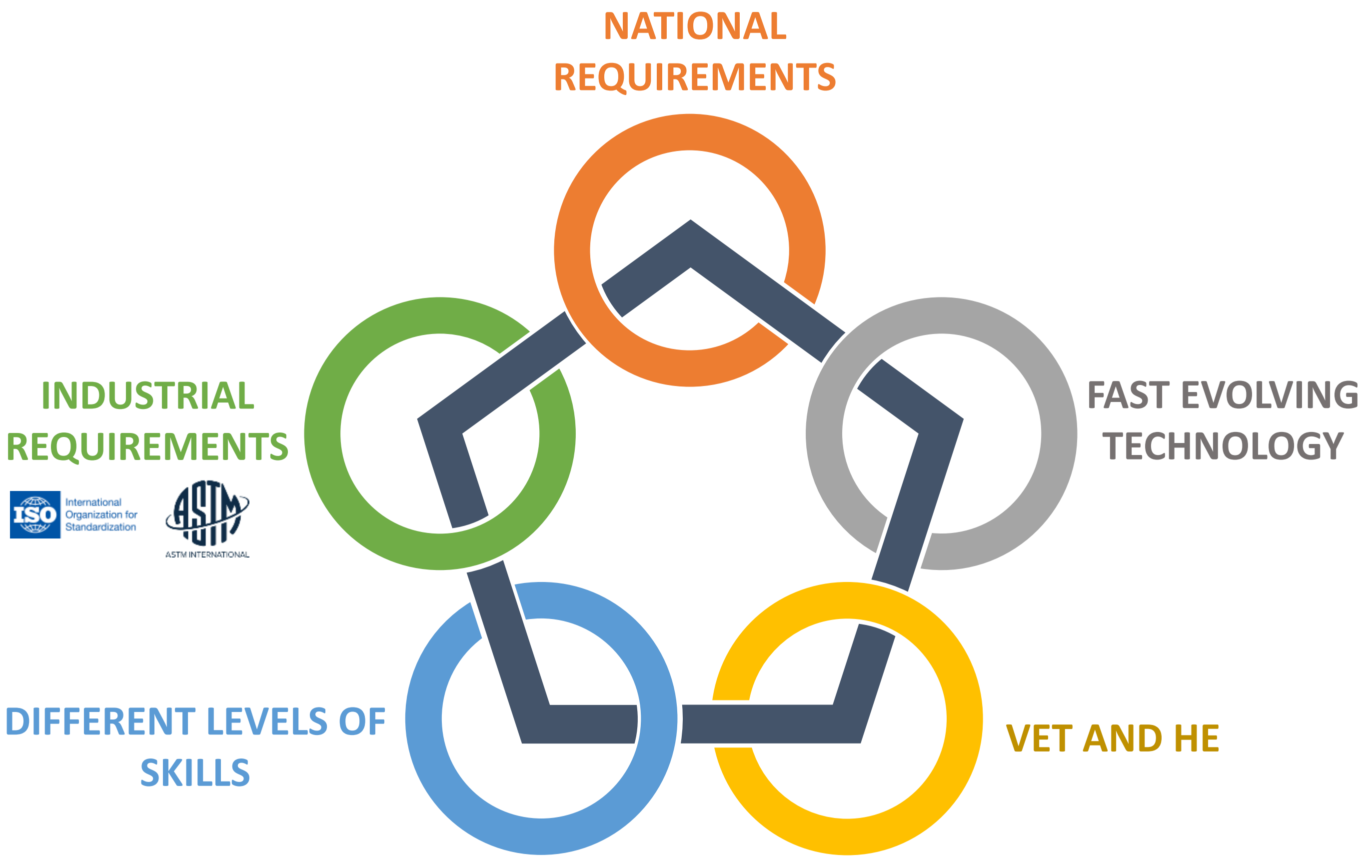
Learning Outcomes – CU 00: Additive Manufacturing Processes Pverview	
KNOWLEDGE	Factual and broad knowledge of theory, principles and applicability of: – Directed energy deposition – Powder bed fusion – Vat photopolymerization – Material jetting – Binder jetting – Material extrusion – Sheet lamination
SKILLS	Distinguish parts produced by different AM processes Recognise the advantages and limitations of AM processes from a manufacturing process chain point of view Identify the applicability of different AM processes, according to the characteristics of each process

Learning outcomes

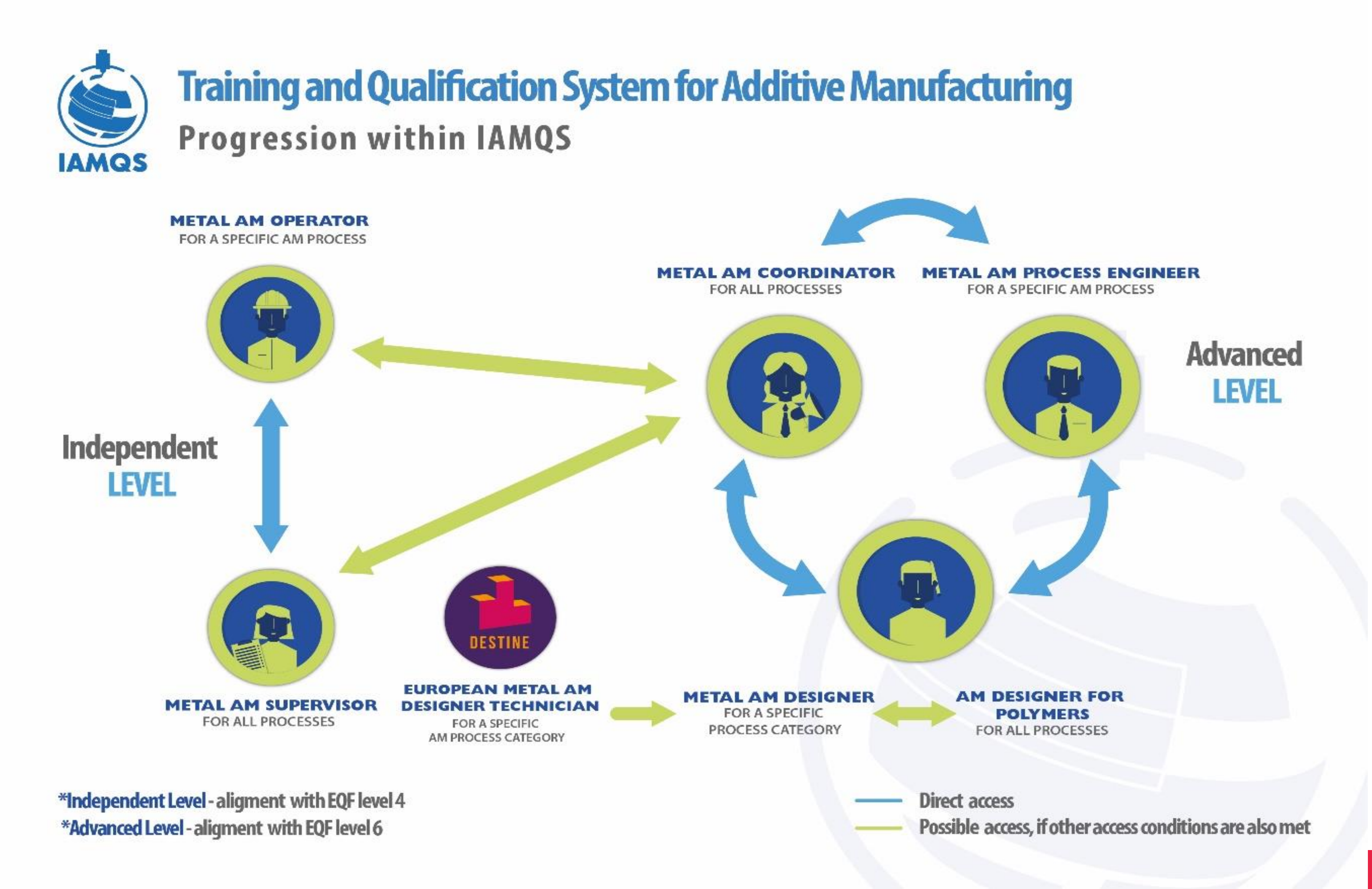
Qualification

AM MODULAR SYSTEM

Qualification



Qualification



Qualification

Qualification in AM is…

…the formal outcome of a a training and assessment process which is obtained when an individual has achieved the skills and knowledge defined in an AM educational programme.
It is valid for life.

CERTIFICATION

Certification

Why certify?

Safety

- Consumers
- Operators
- Members of the public
- Assets
- Environment

Flixborough disaster – 1974
28 lives lost, 36 non-fatal injuries

Concorde – 2000
113 lives lost

Piper Alpha – 1988
167 lives lost

Bhopal disaster – 1984
>3787 lives lost, >500,000 non-fatal injuries

Certification

Safety

- Consumers
- Operators
- Members of the public
- Assets
- Environment

Product assurance

- Industry & market acceptance (safety of product for intended application)
- Confirms legal requirements are met
- Provides assurance of quality and capability to manufacturers, clients and users

Certification

Safety

- Consumers
- Operators
- Members of the public
- Assets
- Environment

Self-certification

- Aerospace: CAA
- Medical: FDA
- Mining: Country specific (e.g. Indian Bureau of Mines)
- Automotive

Product assurance

- Industry & market acceptance (safety of product for intended application)
- Confirms legal requirements are met
- Provides assurance of quality and capability to manufacturers, clients and users

3rd party certification

- Oil & gas
- Marine
- Energy
- Construction

Certification

Difference, between **verification** and **validation:**

- **Verification**: are all the right things in there?
- **Validation**: are all the things in there, right?

- For example, if assessing a spreadsheet, then:
  - verification would involve checking that all required formulas were entered correctly in order to calculate the required outputs (i.e. auditing)
  - validation would involve checking that the values were calculated correctly, usually by use of specific test cases (i.e. testing)

Certification

The formal process of assessing and recognising role specific competences when performing AM activities in line with industrial requirements. It is valid for a specific period and must be renewed to be maintained.

“Qualification is possible without certification but certification requires qualification”

Confusion sometimes arises since a certificate is issued for both certification and qualification - unfortunately, there is no such thing as a qualificate!

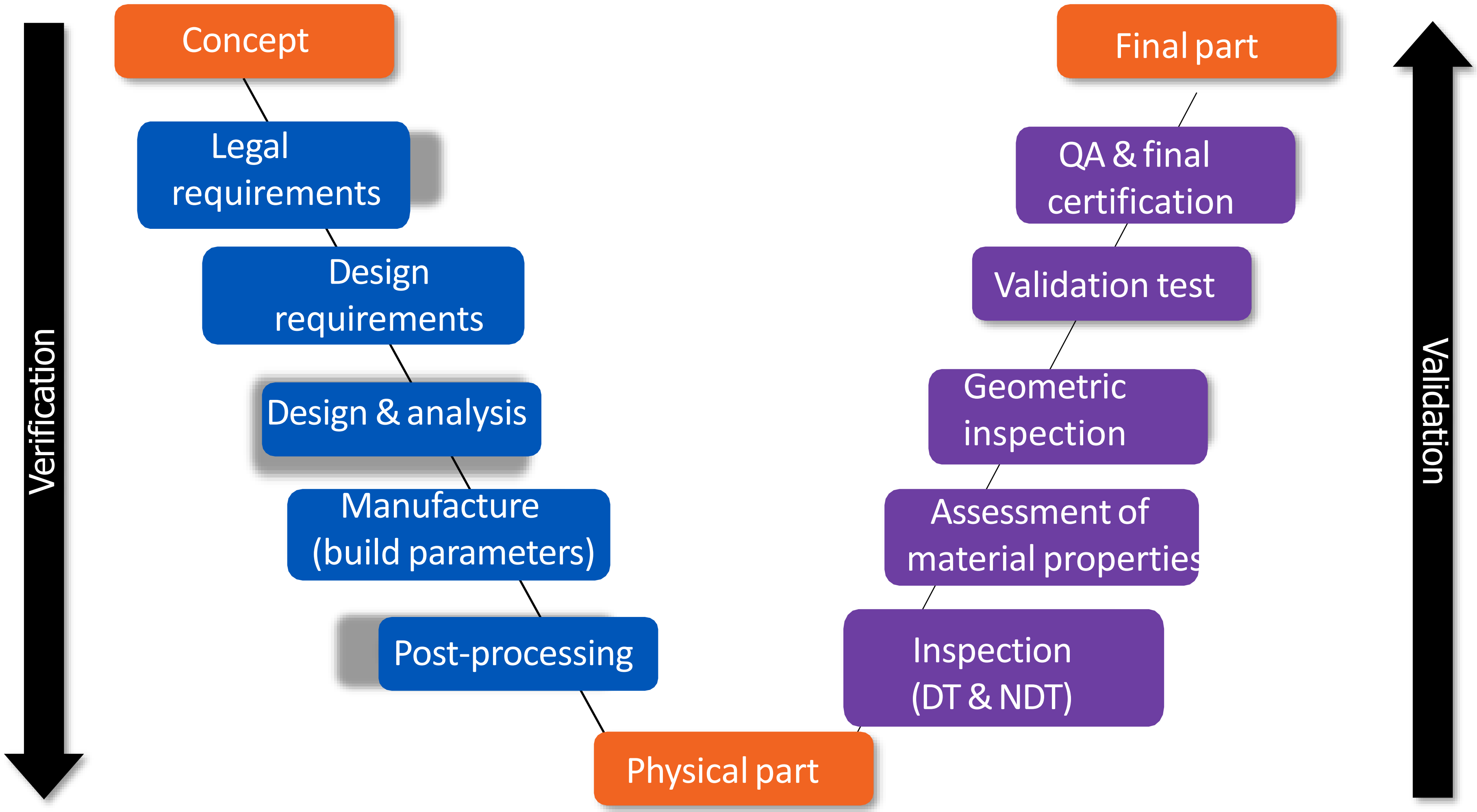
Certification

So, in terms of additive manufacturing…

- A qualified facility is one that **has been verified** as having the necessary equipment, personnel, processes, etc. to produce the outputs that they have been qualified for;

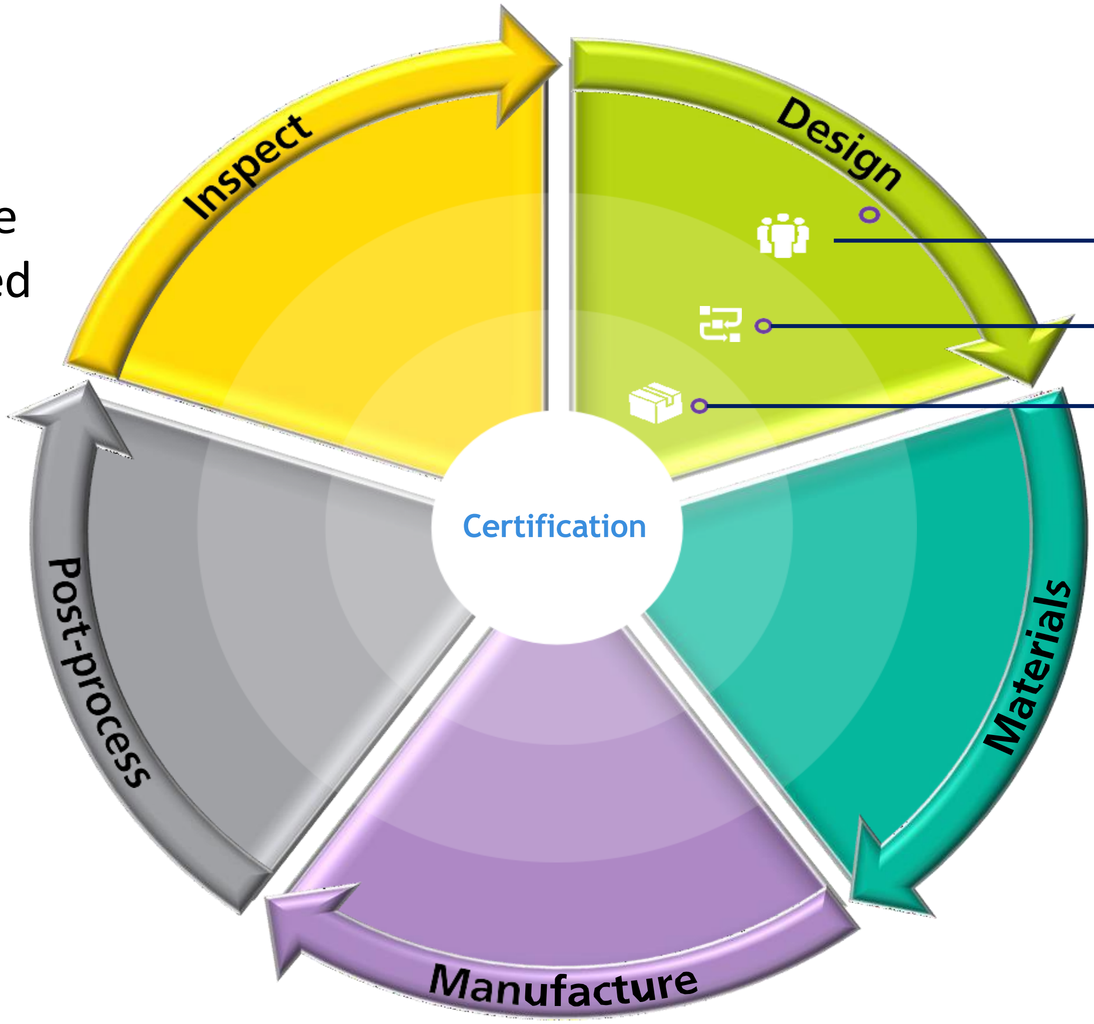
- Certified materials & parts are the outputs from a qualified facility that have been validated as satisfying the requirements of a specific regulation, code, standard or specification;

Certification



Certification

Within each area of activity, the tasks can be further sub-divided into:



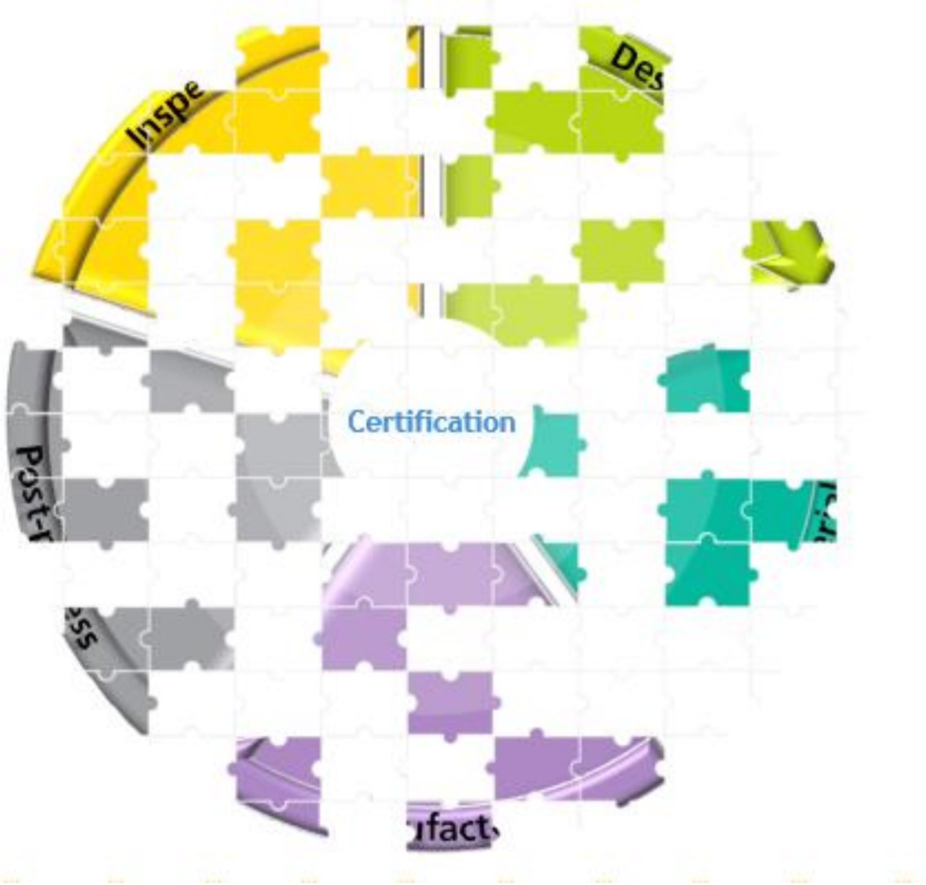
People
Process
Product

...and of course, quality control needs to be applied throughout each functional stage.

Certification

Application specific standards

- Aspects of these can be used for AM, where relevant
- AM-specific information is not typically provided in these standards at the moment
- Questions arise, for example:
    - What material properties to use?
    - Is a design factor required?
    - Are existing fatigue curves applicable for A
    - Are current inspection techniques capable detecting AM-specific flaws?
    - Are AM builds repeatable? What are the causes of variation?



Certification

Application specific standards

- Aspects of these can be used for AM, where relevant
- AM-specific information is not typically provided in these standards at the moment
- Questions arise, for example:
  - What material properties to use?
  - Is a design factor required?
  - Are existing fatigue curves applicable for AM?
  - Are current inspection techniques capable of detecting AM-specific flaws?
  - Are AM builds repeatable? What are the causes of variation?

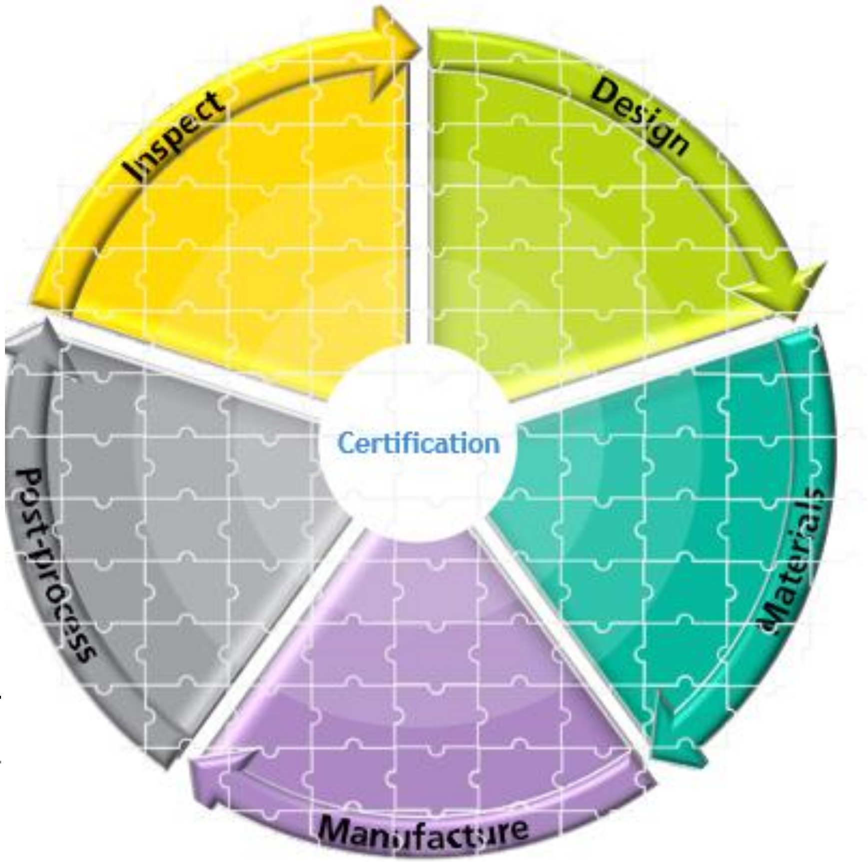
AM specific standards

- Fills the gaps within the industry standards for AM
- Not many AM-specific standards available yet

Certification

Application specific standards

- Aspects of these can be used for AM, where relevant
- AM-specific information is not typically provided in these standards at the moment
- Questions arise, for example:
  - What material properties to use?
  - Is a design factor required?
  - Are existing fatigue curves applicable for AM
  - Are current inspection techniques capable o detecting AM-specific flaws?
  - Are AM builds repeatable? What are the causes of variation?



AM specific standards

- Fills the gaps within the industry standards for AM
- Not many AM-specific standards available yet

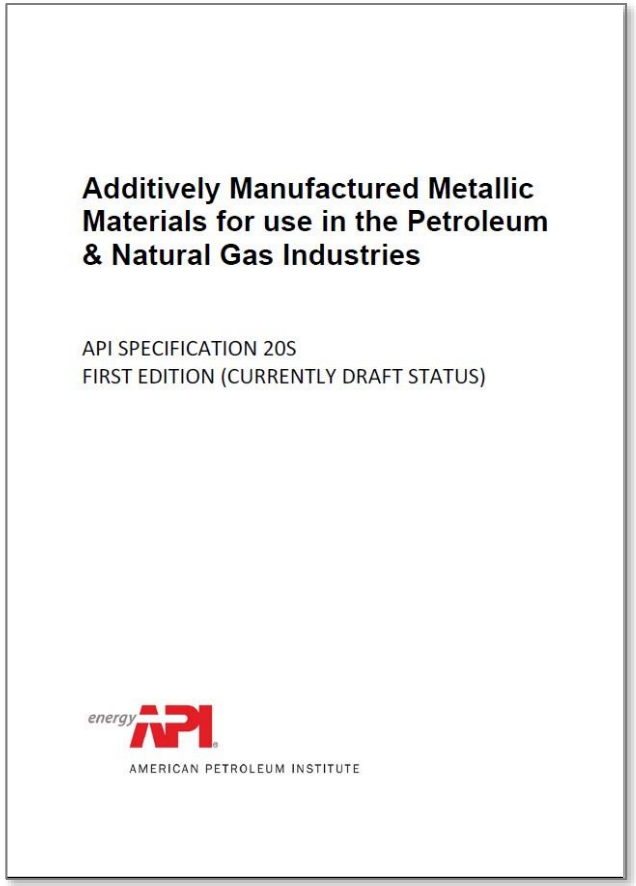
Technology Qualification

- Used where neither industry-specific nor AM-specific standards are available
- Guidance provided by Regulator or Inspection Authority

Certification

API 20S: AM metallic materials for use in the petroleum & natural gas industries

- The API 20S Standard is designed to play a crucial role in leveraging Additive Manufacturing (AM) to foster innovation in the oil and gas industry and encourage a safer, broader, and faster adoption of AM technologies in the mainstream oil and gas applications.


Additively Manufactured Metallic Materials for use in the Petroleum & Natural Gas Industries

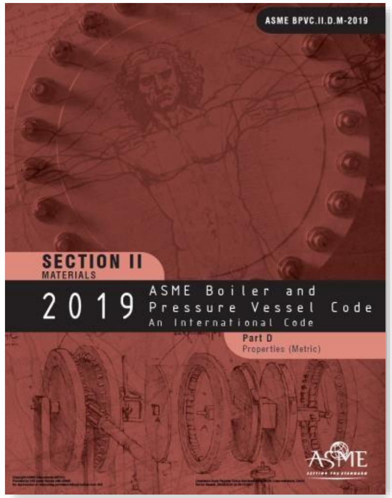
API SPECIFICATION 20S
FIRST EDITION (CURRENTLY DRAFT STATUS)

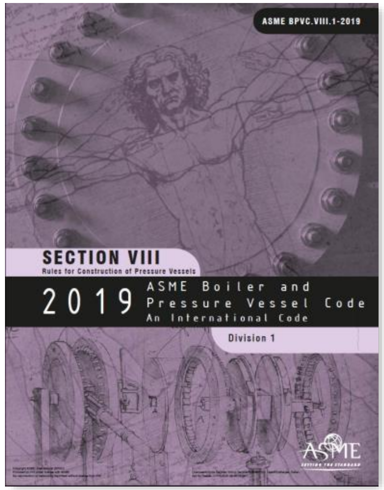
energy API
AMERICAN PETROLEUM INSTITUTE

Certification

ASME BPTCS/BNCS Special Committee

- Charter: to develop a technical baseline to support development of a proposed BPTCS standard or guideline addressing the pressure integrity governing the construction of pressure retaining equipment by additive manufacturing processes. Construction, as used in this Charter, is limited to materials, design, fabrication, examination, inspection, and testing.
- Scope is limited to powder bed fusion (laser and electron beam energy sources) at the moment (DED-Arc to follow).
- Once approved, the criteria will be published as a Pressure Technology Book (PTB) and used as a reference document for proposals for AM Code Cases or incorporation of AM into construction codes.

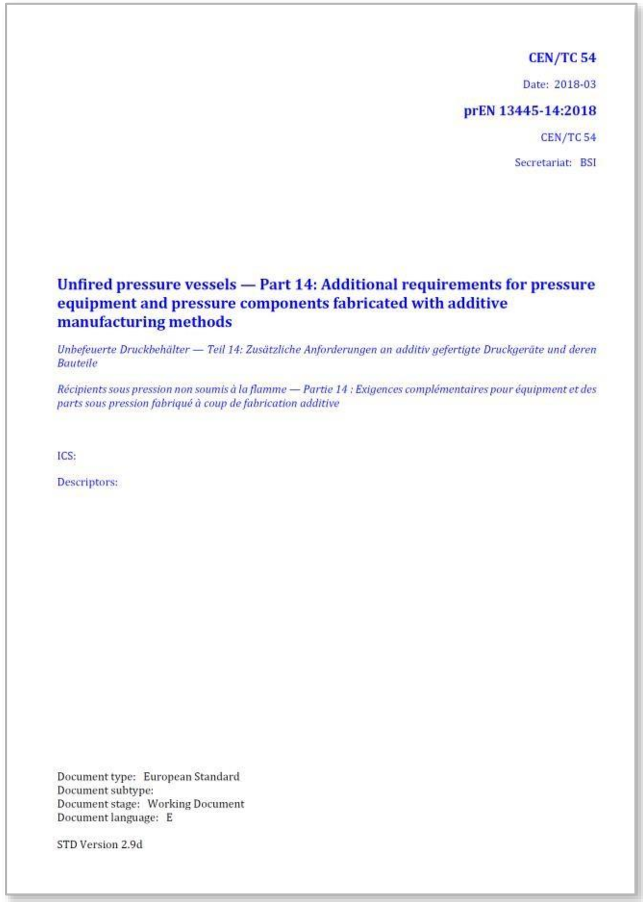




Certification

CEN/TC 54: Unfired pressure vessels

- **EN 13445 Part 14** has been drafted a new to incorporate requirements for pressure components by AM
- Includes sections on:
  - Materials (including nominal design stress rules)
  - Design & fabrication rules (including documentation & identification)
  - Inspection & testing (including Quality Factor for different levels of NDE)
  - Separate annexes for different AM processes (e.g. Annex A for powder bed fusion; Annex B for direct energy deposition with wire; etc.)
  - Each annex further sub-divides by specific material requirements (e.g. B.1 General requirements for DED-wire; B.2 DED-wire and steel; B.3 DED-wire and aluminium; etc.)



CEN/TC 54

Date: 2018-03

prEN 13445-14:2018

CEN/TC 54

Secretariat: BSI

Unfired pressure vessels — Part 14: Additional requirements for pressure equipment and pressure components fabricated with additive manufacturing methods

Unbefeuerte Druckbehälter — Teil 14: Zusätzliche Anforderungen an additiv gefertigte Druckgeräte und deren Bauteile

Récipients sous pression non soumis à la flamme — Partie 14 : Exigences complémentaires pour équipment et des parts sous pression fabriqué à coup de fabrication additive

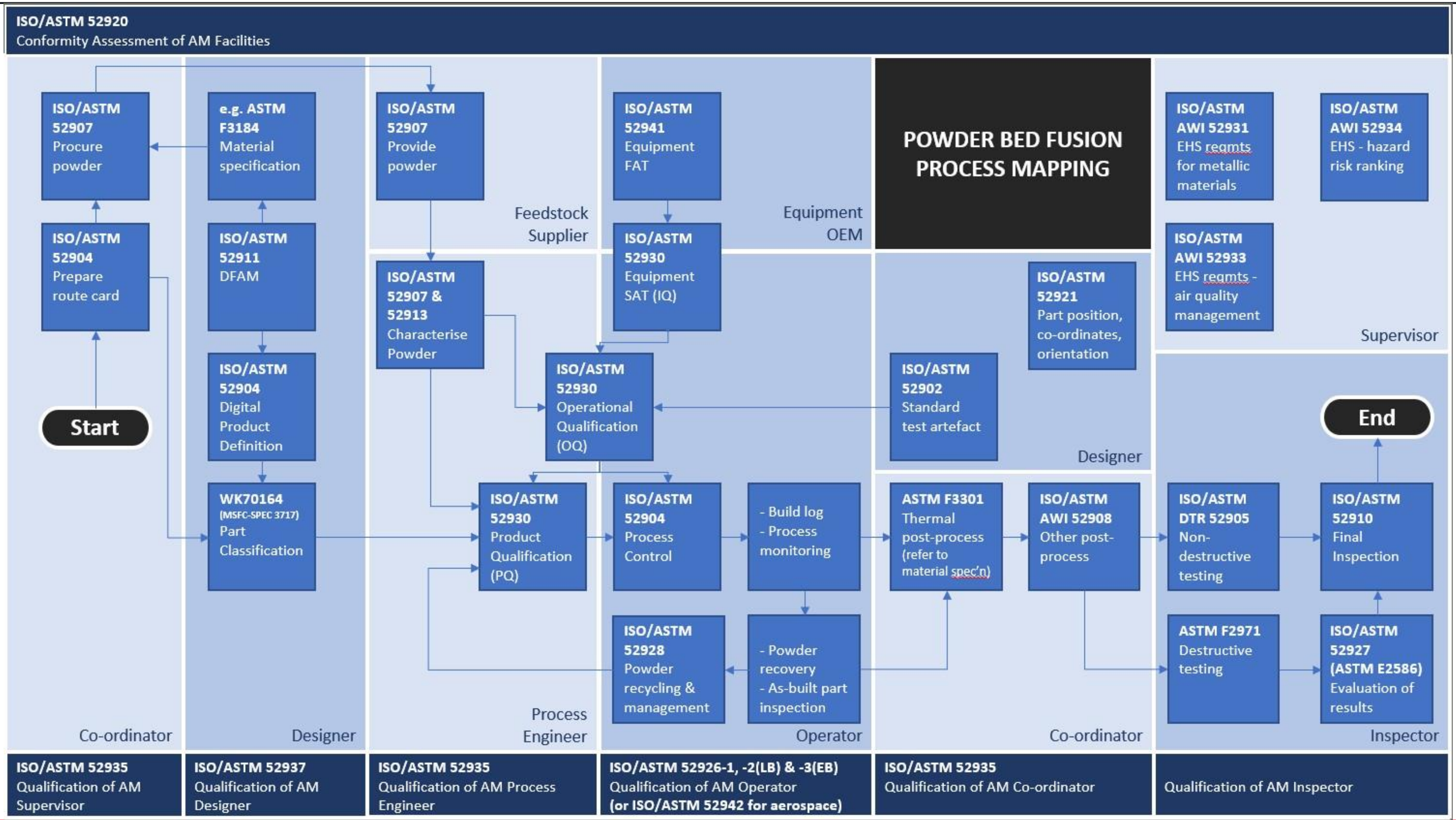
ICS:

Descriptors:

Document type: European Standard
Document subtype:
Document stage: Working Document
Document language: E

STD Version 2.9d

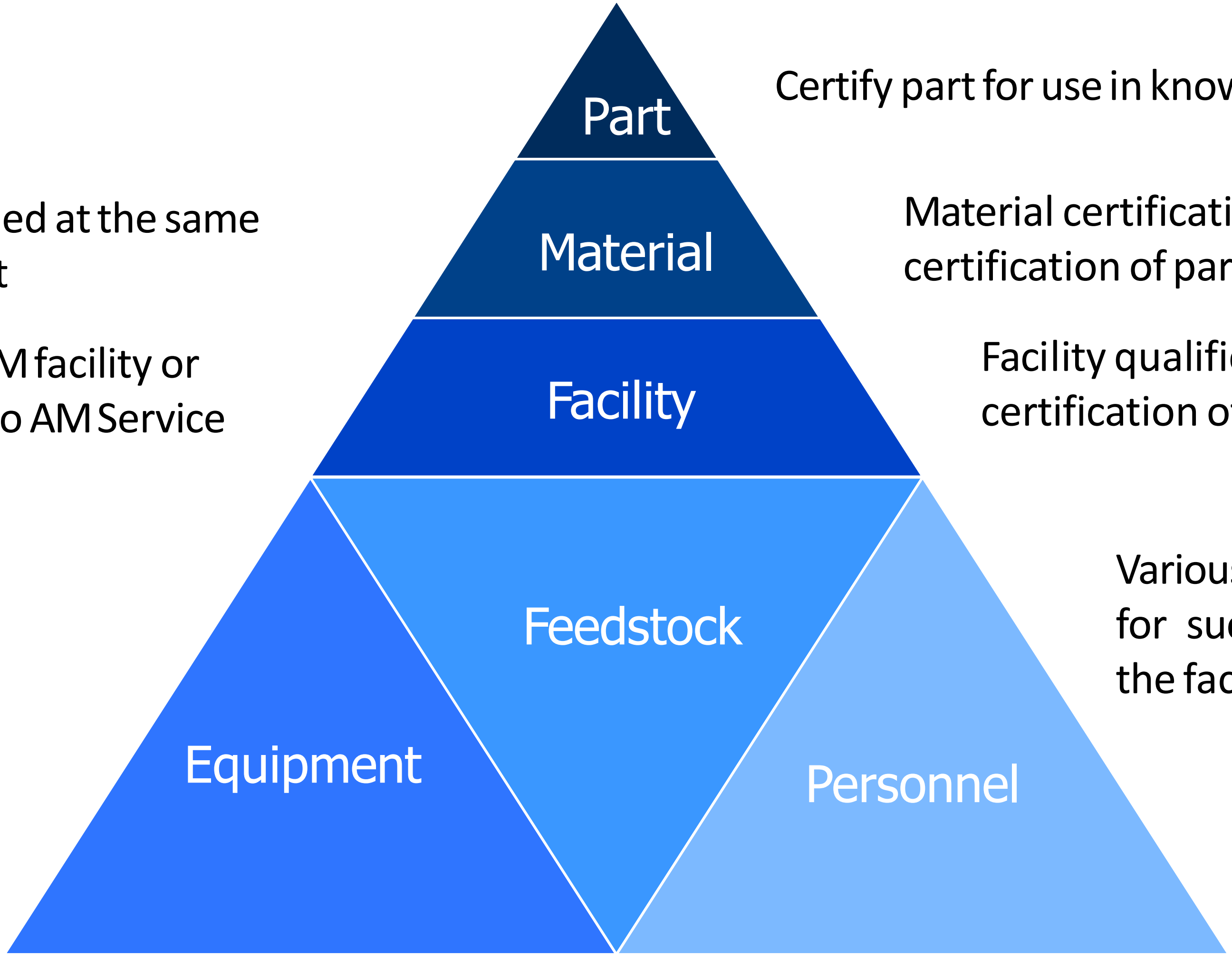
Certification



Certification

In AM, the material is formed at the same time as producing the part

This may be an in-house AM facility or could be sub-contracted to AM Service Bureau



Certify part for use in known application

Material certification is pre-requisite for certification of part

Facility qualification is pre-requisite for certification of part and material

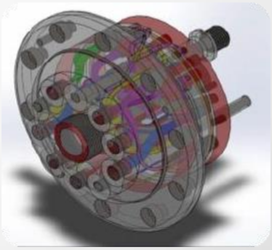
Various under-pinning aspects for successful qualification of the facility

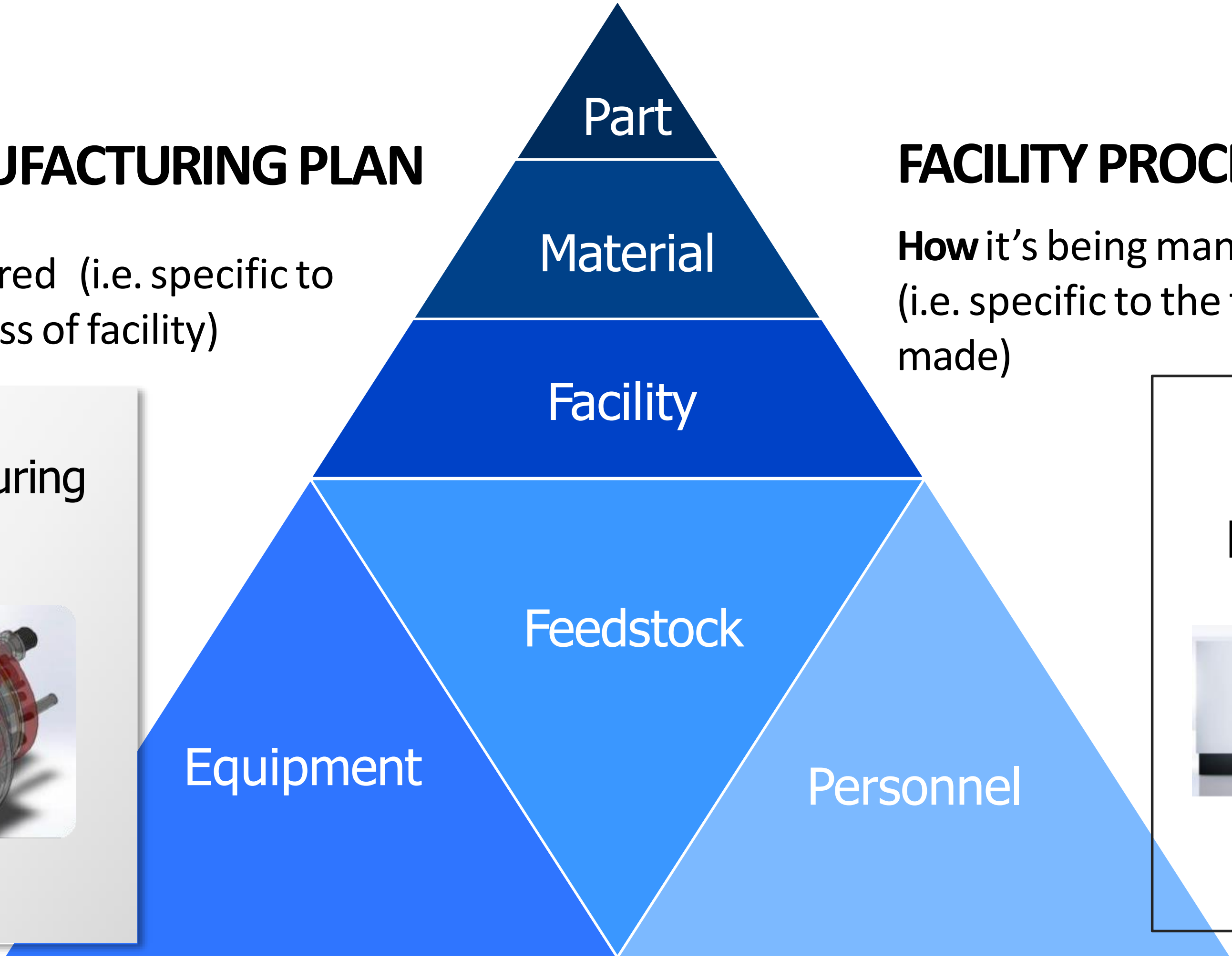
Certification

MANUFACTURING PLAN

What is being manufactured (i.e. specific to the part, almost regardless of facility)

Manufacturing Plan

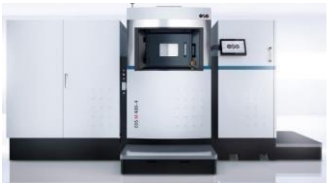




FACILITY PROCEDURES

How it's being manufactured
(i.e. specific to the facility, regardless of what is being made)

Facility Procedures



Certification

Why do we need personnel qualifications for AM?

Material specifications require it:

- EN 764-5 (metallic materials for pressure equipment)

e) The competent body shall evaluate by interviews or by the examination of documents:

1) that the manufacturing equipment and the equipment controlling the essential parameters are available. They shall be capable of permitting the consistent delivery of products in the required quality;

2) that competent personnel are available for operating and maintaining the equipment and supervising the manufacturing and inspection and testing activities;

Product standards require it:

- EN 13445-1 (unfired pressure vessels - general)

— the welder or welding operator shall be qualified, see 7.4 of EN 13445-4:2009.

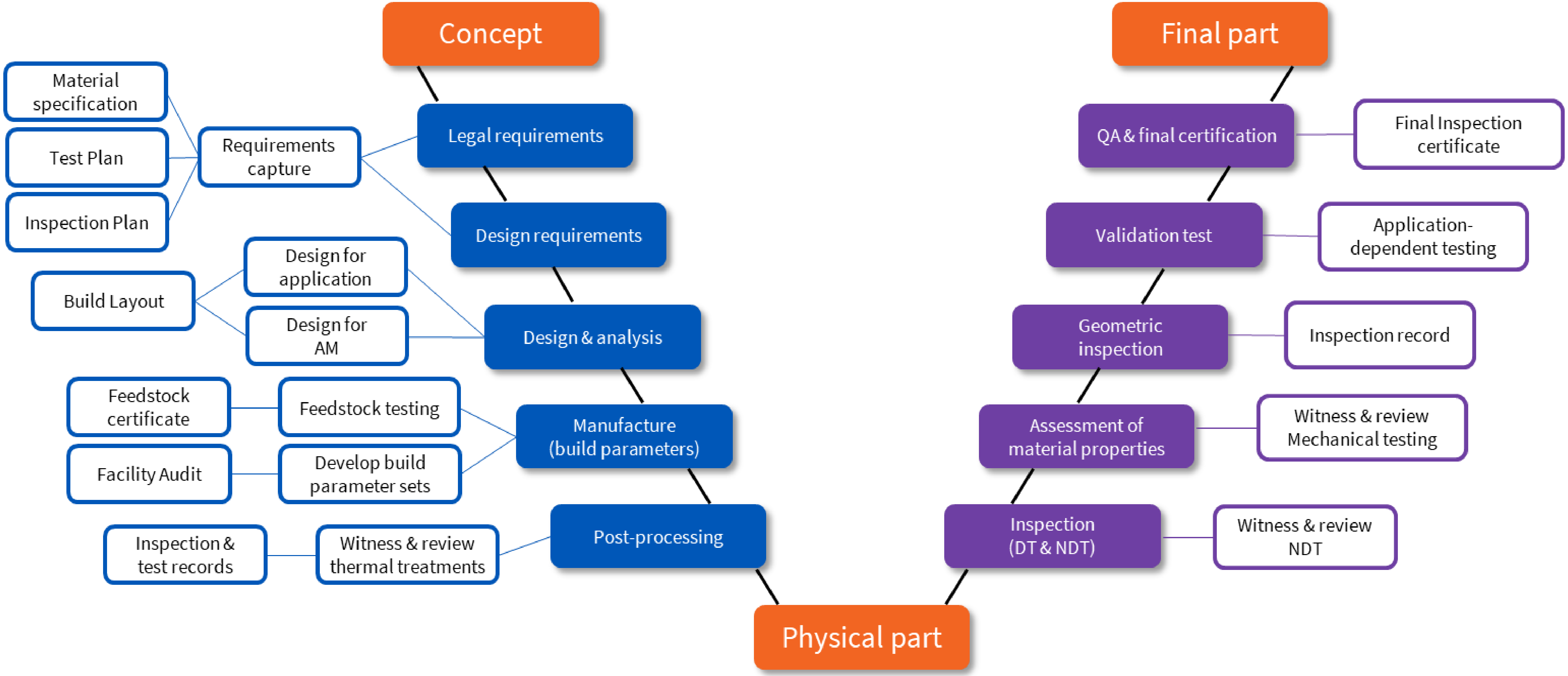
- EN 13445-3 (design)

Due to the advanced methods applied, until sufficient in-house experience can be demonstrated, the involvement of an independent body, appropriately qualified in the field of DBA, is required in the assessment of the design (calculations) and the potential definition of particular NDT requirements.

- EN 13445-5 (inspection)

All inspections shall be carried out by qualified personnel.

Certification



Certification

- Design Appraisal Document
  - o Assessment of design against required regulatory, code and/or standards requirements
  - o Independent calculations and assessment of build layout
  - o Statement of Endorsement can be issued prior to progressing with build
- Material (powder, wire) certification
  - o Witnessed material testing
  - o Inspection report issued (to powder vendor or manufacturer, depending who performs the required testing)
- Additive manufacturing facility certification
  - o Facility audit
  - o Review of existing approvals, processes & procedures
  - o Issue AM Quality Scheme Approval Certificate

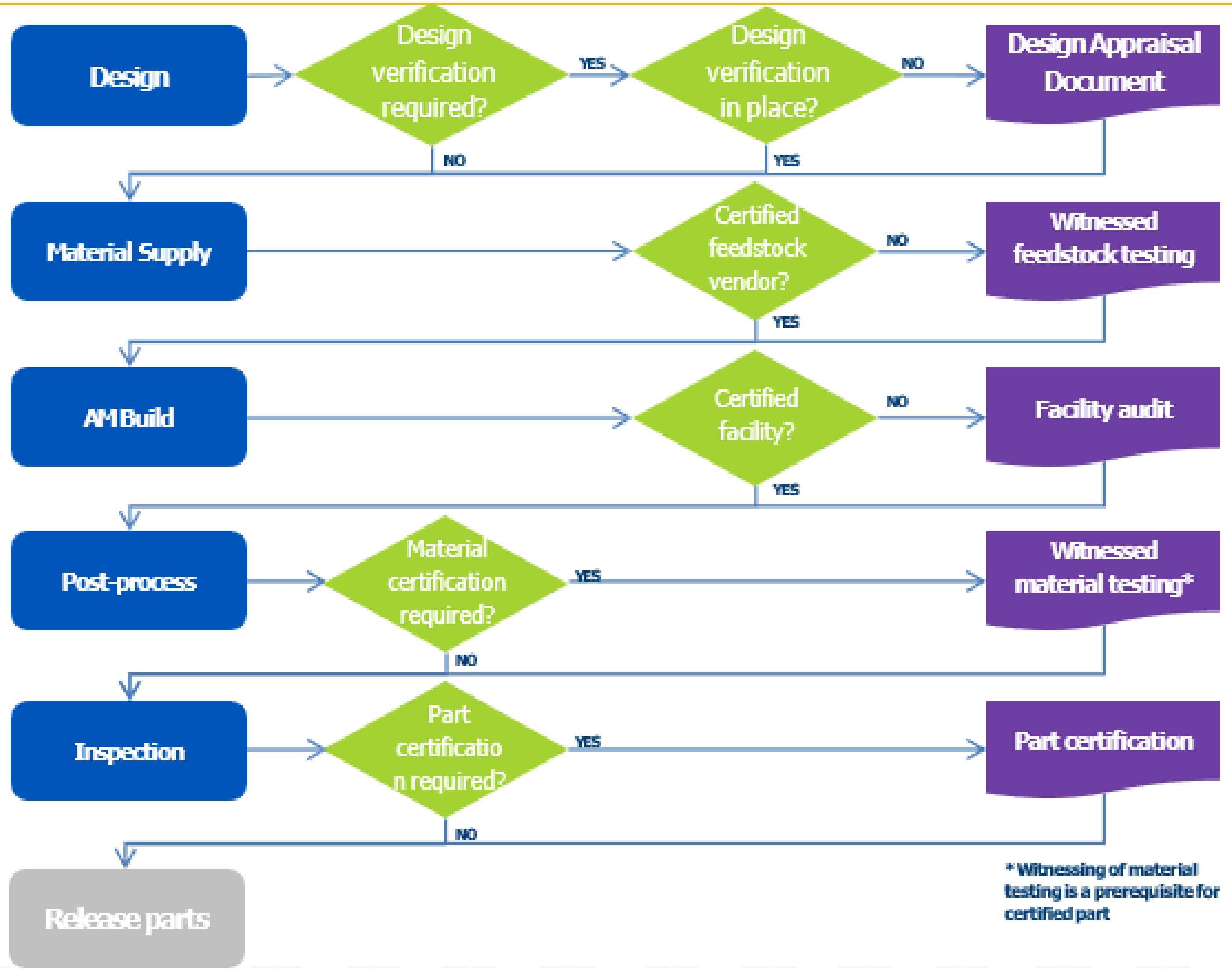
Certification

- Post-process & inspection facility
  - o Witnessed material testing
  - o Material certification (formed material)
  - o Inspection report issued

- Part certification
  - o Limited in scope to the design, material, facility & manufacturing instructions used
  - o Changes to any part of the process would require re-validation of the part certification

Certification

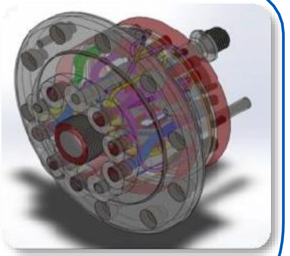
- Different organisations within the supply chain may perform activities within each functional stage
- Specific certification can be provided for each stage, which can then reduce the effort required for subsequent part design
- Using pre-qualified facilities can enable part manufacturers to reduce cost and lead times for part certification



Certification

Rolls-Royce
ENGIE Laborelec
中广核 CGN 核能
Suzhou Nuclear Power Research Institute
Chevron
SULZER
BR PETROBRAS
Sellafield Ltd
ConocoPhillips
中国航发 AECC — Aero Engine Corporation of China
BIAM — Beijing Institute of Aeronautical Materials
AVIC MANUFACTURING TECHNOLOGY INSTITUTE

Joint Industry Projects



AM Part Certification

Shell
AML3D
3D METAL FORGE
TWI
wipro
eos
ENGIE

AM Facility Qualification

CLLAIM
Keppel
Nanyang Technological University
Shell
Schlumberger
Singapore Polytechnic SP
Universidade Federal do Rio de Janeiro
FLOWSERVE

Consultancy & Training

EWF
ASME — Setting the Standard
ISO
ASTM
cen

Knowledge Sharing

CU 63 – Certification, Qualification & Standardisation
(Based on D. Hardacre presentation)

CQS IN PROCESS CHAIN

CQS in Process Chain

EN 9100 (8.5.1.2 Validation)
For processes where the *resulting output cannot be verified by subsequent monitoring or measurement*, the organization shall establish arrangements for these processes

IATF 16949 (8.3.4.2 Validation)
During validation, it is examined *whether the product produced in this way* (e.g. within the framework of the prototype program) *meets the product requirements*.

ISO 13485 (7.5.6 Validation)
The organization shall *validate any processes for production* and service provision *where the resulting output cannot be or is not verified by subsequent monitoring or measurement*

CQS in Process Chain

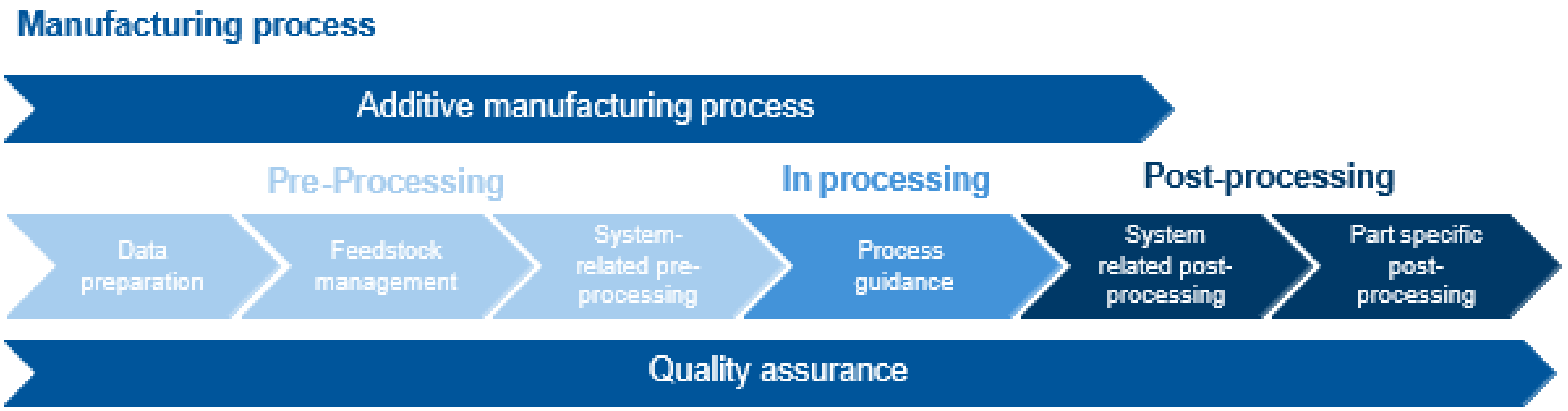
Risk management system which targets application & AM technology specific risks

1. **Application centric view:**
   Surface roughness + Powder removability + Sterilization + Design Verification + Material property etc.

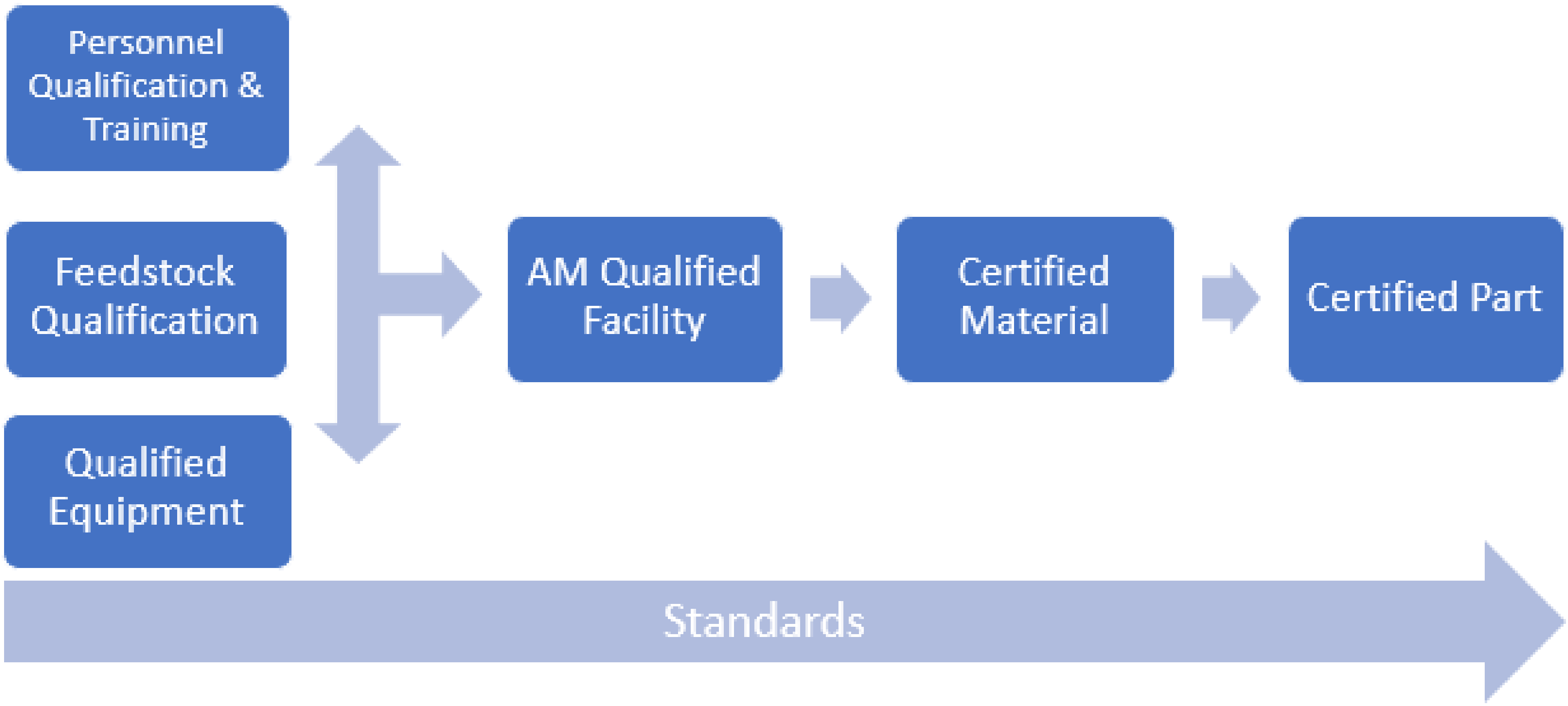
2. **AM technology risks needs to be eliminated via quality assurance & standards:**
   AM build process anisotropy, Feedstock management, Quality assurance of working steps

CQS in Process Chain

Exemplary AM specific Quality Managment System according
I S O / A S T M DIS 52920



CQS in Process Chain



CQS in Process Chain

Personnel Qualification/Certification

- Standards under development:
  - ISO/ASTM 52926 Series (Qualification of Machine Operators)
  - ISO/ASTM 52935 (Qualification of AM Co-ordinators)
  - ISO/ASTM 52937 (Qualification of AM Designers)
- OEM Training
- On the job training
- Awareness of Health and safety
- Maintaining records

CQS in Process Chain

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

CLLAIM Project

Creating knowLedge and skilLs in AddItive Manufacturing

- ✓ International AM qualification body
- ✓ International harmonized Qualification System
- ✓ Qualifications by profiles (Designer, Operator, Supervisor and Inspector)

8 Partners → 4 Countries → 1 EC Project Officer

CESOL · EWF · TWI · DVS German Welding Society · Laser Akademie · Fraunhofer IWU

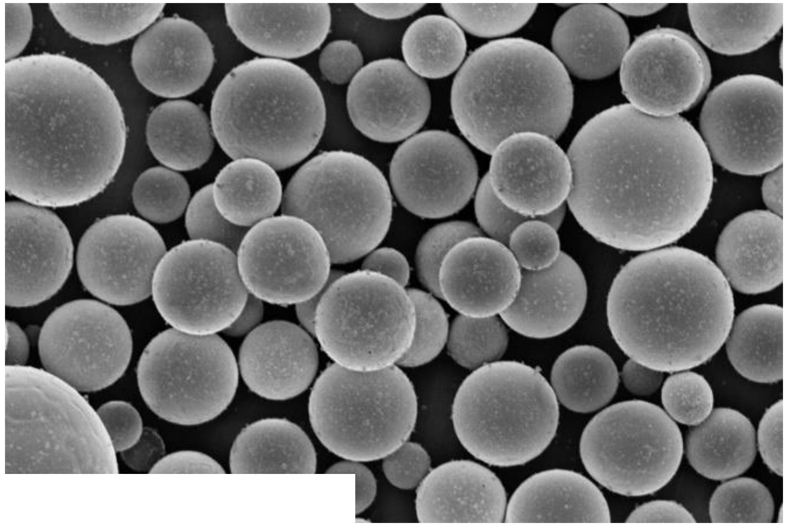
Assessing, targeting industrial skills needs and creating the necessary Qualifications Profiles

IDONIAL Centro Tecnológico · Lloyd's Register

Industrial Processes and AM product's certification

CQS in Process Chain

Feedstock Qualification



- Use specification
- Purchase specification
- Testing
- Procurement

CQS in Process Chain

Feedstock specification

- External provider
- SS316L enhanced - agreed with sponsors
- Meeting specification requirements

Feedstock procurement

- Eight potential vendors contacted, three offers to supply
- Powder supplier accredited by a Certification Authority
- Certificate of conformity and MSDS

Sampling

- Production quantity purchased = 200kg (20 x 10kg bottles)
- As per ASTM B215-15 recommendations
- Samples removed from 7 randomly selected bottles, combined and sent for analysis

Recycling

- Powders sieved (<63µm) after every use and powder samples taken
- Powders re-analysed (complete re-certification) after every 3rd recycle

CQS in Process Chain

- Chemical composition
- Flowability (Hall flowmeter)
- Apparent (Scott) density
- Tap density
- Particle size analysis via laser diffraction
- Morphology (optical / SEM)

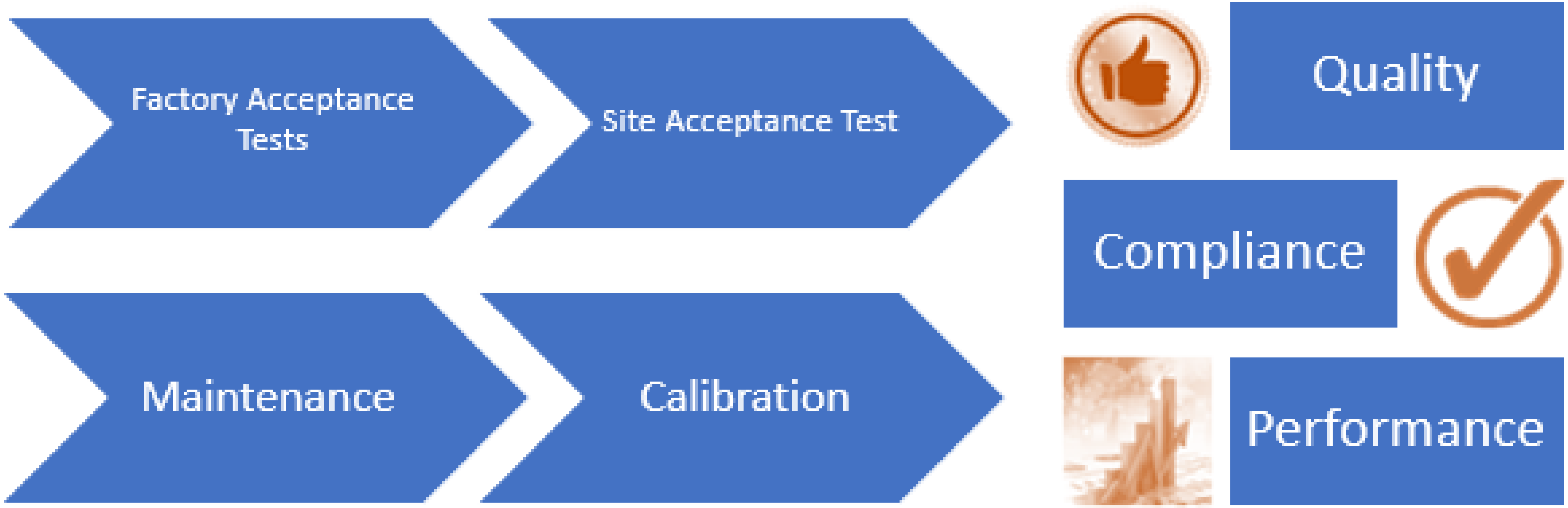
Powder Testing/Characterisation

All powder characterisation tasks sub-contracted (UKAS approved on chemical and particle size determination)

ation

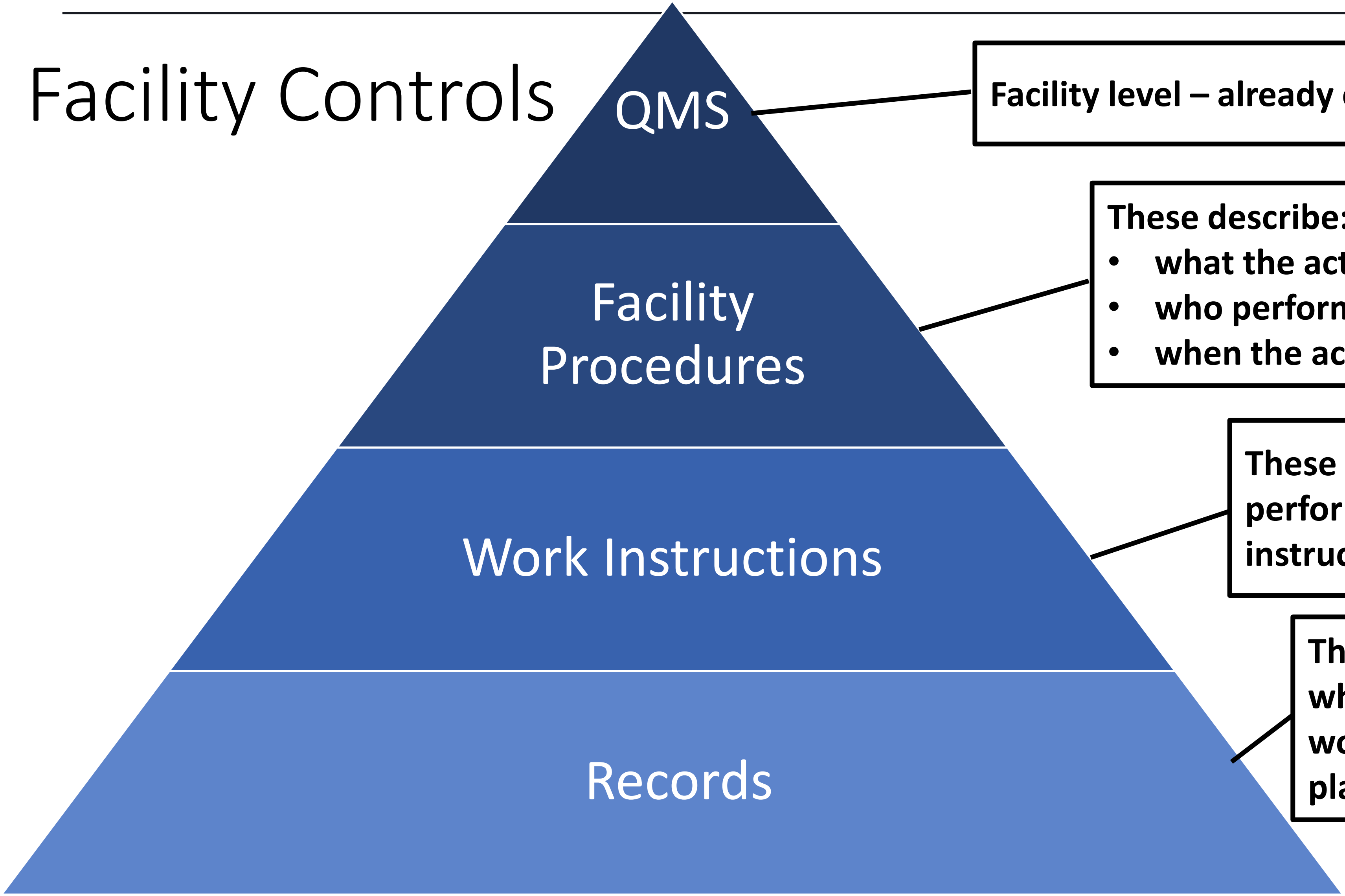
CQS in Process Chain

Qualified Equipment



CQS in Process Chain

Facility Controls



Facility level – already covered by ISO 9001

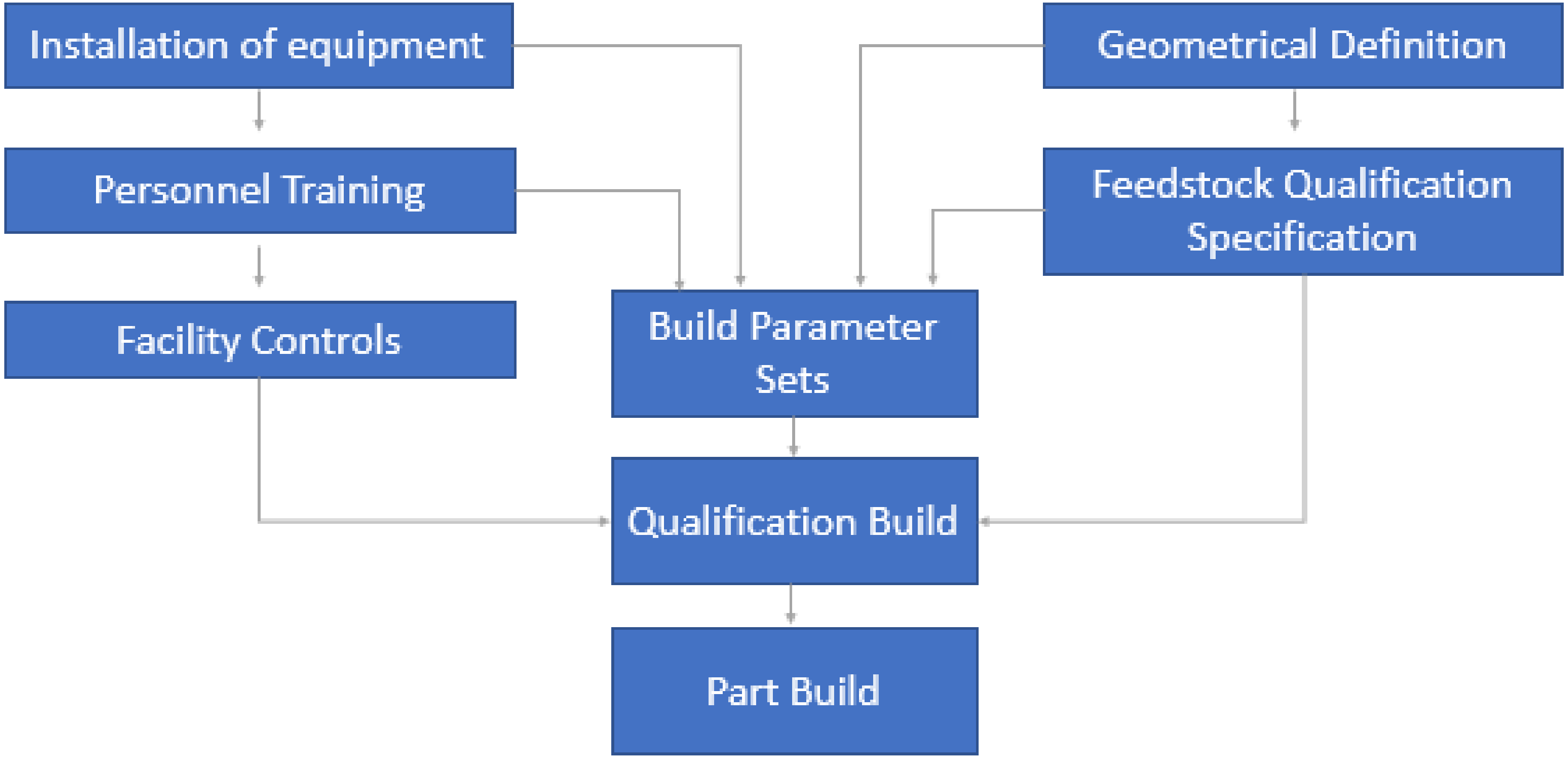
These describe:
- **what the activities are**
- **who performs the activities**
- **when the activities are performed**

These describe how the activities are performed (more detailed, step-by-step instructions – should start with a verb)

These capture specific details when performing the activities in a work instruction (e.g. build platform thickness check)

CQS in Process Chain

Manufacturing Flowchart



CQS in Process Chain

Benifits of a certified process

Qualification time saving and Cost reduction

Reduced technology and investment risk with reproducible AM system

Complying with requirements of regulated industries

CONTACTS

- **Email:** pcatarino@ewf.be
- **Tel.** +351 913 027 363
- Av. Dr. Mário Soares 35, 2740-119 Porto Salvo
  Portugal