



GE Additive

Achieving Qualification

The Path to Production

Achieving Qualification

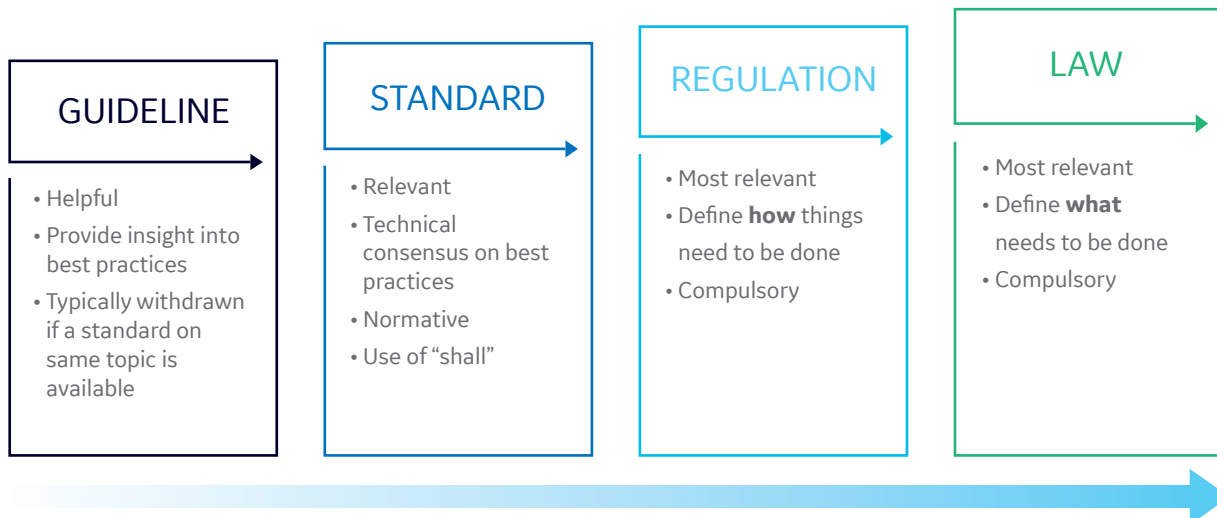
Achieving qualification and certification for your organization is an enormous milestone on the path to production in additive manufacturing. Understanding the appropriate application of standards, guidelines, and regulations may allow your business to have a competitive advantage by:

- Helping to facilitate certification and conformity in assessment requirements
- Potentially reducing your organizations R&D and production costs
- Proactively managing quality to reduce cost, inconsistencies in production, and the cost associated with waste
- Helping to improve your overall equipment effectiveness yield, and reduce machine to machine variation

The Basics: A simplified ranking of different document types

Standards (public and private) are developed to define how things “shall” be done to achieve compliance in regulated industries. However, every industry is different; therefore, every industry has its own path to achieve qualification and move into additive production. An optimum approach in industry standards development includes:

- Adapt conventional standards (if partly applicable)
- Do not “re-invent the wheel” involve right people with right expertise
- Documents not too wide or too academic
- Reach consensus
- Involve certification bodies



NOTE: Our services for applications in the healthcare industry may be limited and will require additional review.

Courtesy of Fraunhofer IGCV

A framework for additive qualification

The fundamental goal in additive qualification is successfully planning how you will implement production readiness that spans the entire ecosystem of additive—from design to finished part.

Machine and Material qualification involves demonstrating compliance a machine acceptance specification and demonstrating compliance to the final material specification.

Process qualification includes demonstrated compliance to the powder (raw material) specification, and the compliance to the process specification with its referenced process control documents.

Design qualification is determined by the part application requirements and design standards. Within the design qualification is the material allowable database,

which is important for high criticality parts and often includes material property data like fatigue and fracture.

Part qualification helps with gaining regulatory and legal certification. The finished part or application includes process controls and manufactured part quality control to repeatedly achieve the same mechanical and/or structuring properties, process control variations, and inspection specifications on the machine.

Certification is based on meeting regulation and legal requirements in your industry.

Keep in mind, even though public standard organizations have completed much of the required work towards certification of AM parts, it’s still not enough to ensure the part will be certified. Take for example the aviation industry, some parts have yet to be certified for air flight. Below are some examples.

Qualification	Policy, Specs, Standards, Database, Documents	Example	Industry	Proprietary
Design	Design standards	OEM		
Design	Material property database	MMPDS		
Machine & material	Machine acceptance standard	ISO		
Machine & material	AM material & process specs	SAE		
Process	Manufacturing process control documents	OEM		
Part	Inspection standards	ASTM		
Part	Quality specs	ISO		
Certification	Regulations & rules	FAA FAR		
Certification	Policy & guidance	FAA AC		

Not available Content exists, but incomplete for regulated qualification Content available

What to consider when using standards

When considering the use of standards in AM there are some key things to consider:

- Understand the regulations before selecting the appropriate standards
- Recognized industry standards can be extremely useful, but requires propriety data and documents for regulated industries
- You must demonstrate that the combined set of industry standards and proprietary documents you developed work together as a system

Remember, the appropriate application of standards is critical to achieving the desired outcome.

