

ISO/ASTM 52920:2023-06 (E)

Additive manufacturing - Qualification principles - Requirements for industrial additive manufacturing processes and production sites

Contents		Page
Foreword		v
Introduction		vi
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	Overview of AM related processes	2
5	Infrastructure of the part manufacturer	3
5.1	Environmental, health and safety (EHS)	3
5.2	Waste disposal	3
5.3	AM system installation	3
5.4	Ancillary equipment	4
5.5	Feedstock storage	4
5.6	IT infrastructure	4
5.7	Foreign object debris (FOD)	4
5.8	Provision of the process resources	4
5.9	Manufacturing management system	5
5.10	Maintenance/calibration system	5
6	Manufacturability assessment and review	5
6.1	General	5
6.2	Design assessment and review	5
6.3	Manufacturing assessment and review	6
6.3.1	Additive manufacturing process	6
6.3.2	Process finalization	6
6.3.3	Post processing	6
7	Qualification of the additive system operations	6
7.1	General	6
7.2	Scope of qualification	7
7.3	Validation planning	7
7.3.1	Process mapping	7
7.3.2	Risk assessment	7
7.3.3	Master validation plan	8
7.4	Qualification [installation, operation, and performance (IQ/OQ/PQ)]	8
7.5	Manufacturing plan specification	9
7.6	Documentation and tracing of the process steps	10
7.6.1	General	10
7.6.2	Manufacturing plan	10
7.6.3	IQ documents	10
7.6.4	OQ/PQ documents for the complete process	11
7.7	Relevant process steps within the additive system operations	11
7.7.1	Overview of additive system operations	11
7.7.2	Requirements for pre-process: data preparation	11
7.7.3	Requirements for feedstock management	13
7.7.4	Requirements for pre-process: system set-up	15
7.7.5	Requirements for additive manufacturing: build cycle	16
7.7.6	Requirements for AM-process: process finalization	17

8	Quality assurance	19
8.1	General.....	19
8.2	Personnel requirements.....	19
8.3	Non-conformities	20
	8.3.1 General	20
	8.3.2 Acceptance criteria.....	20
	8.3.3 Handling of non-conformities.....	20
8.4	Continuous improvement process.....	21
8.5	Quality controls	21
	8.5.1 General	21
	8.5.2 Production run approval.....	22
	8.5.3 Part approval.....	23
	Annex A (informative) Requirements for Post-processing and part approval	24
	Annex B (informative) Supplementary information	26
	Bibliography	34