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

Fabrication additive — Principes de qualification — Exigences pour les procédés et les sites industriels de production en fabrication additive

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 261, *Additive manufacturing*, in cooperation with ASTM Committee F42, *Additive Manufacturing Technologies*, on the basis of a partnership agreement between ISO and ASTM International with the aim to create a common set of ISO/ASTM standards on Additive Manufacturing, and in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 438, *Additive manufacturing,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Additive manufacturing increasingly represents an attractive alternative to more conventional manufacturing method for companies. The trend towards complex parts, decentralised manufacturing and customised products allows economically viable application for a wider area. This applies to an increasing number of serial applications, which pose new requirements to the processes' performance. In particular, high quality and safety requirements need to be fulfilled for components used for various applications in several branches of industry, including but not limited to: automotive, mechanical engineering, railway, aerospace, processing plants and medical. Historically, this need has been addressed by the definition of the processes for the manufacturing of parts individually for each case, which entails a high degree of expense, and which permits little transparency and hence little trust amongst stakeholders in the process.

If industrial parts are produced using additive manufacturing techniques, it should be verified that these meet the requirements placed on them. To this end, the process sequence and environment should be designed in a way that the process quality and part quality remain consistent and reproducible at all times.

The document outlines the relevant requirements to establish quality-assured processes in additive manufacturing.

This document has the aim of outlining the requirements as an integral whole (not product specifically), which are necessary as a basis for designing processes for high-quality parts made by additive manufacturing. In particular, in regulated industries, such as the automotive industry, mechanical engineering, the rail sector, aerospace, process and industrial systems or medical technology, consideration of the criteria defined within the framework of this document will establish a basis for fulfilling the requirements for specific products.

Important measures relating to the additive system operations are defined, which are to be controlled and monitored in order to ensure a reproducible quality of AM parts. As this document is not intended to be technology-dependent, the sub-processes are either applicable or can be disregarded, depending on the technology used.

This document provides a common approach for the proper manufacturing of additively manufactured series and replacement parts. In this way, the scope of a supplier audit can be minimised if the requirements of this document are fulfilled.

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

1 Scope

The requirements in this document are for part manufacturers using additive manufacturing techniques and are independent of the used material and manufacturing method.

This document specifies criteria for AM relevant processes as well as quality-relevant characteristics and factors along the additive system operations and defines activities and sequences within an additive manufacturing production site.

This document is applicable to the additive manufacturing technologies defined in ISO/ASTM 52900 and defines quality assurance measures along the manufacturing process.

Environment, health and safety aspects are not covered comprehensively in this document. The corresponding content is addressed in the equipment manufacturer guidelines and ISO/ASTM 52931, ISO 27548[1)], ISO/ASTM 52933 and ISO/ASTM 52938-1[2)].

This document provides requirements that are additional to those provided by a quality management system (such as ISO 9001, ISO/TS 22163, ISO 19443, EN 9100, ISO 13485, IATF 16949). Additionally, this document can be used to establish quality management system relevant content that is specific to AM-technology.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/ASTM 52900, *Additive manufacturing — General principles — Fundamentals and vocabulary*

ISO/ASTM 52950, *Additive manufacturing — General principles — Overview of data processing*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/ASTM 52900 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

1) Under preparation. Stage at the time of publication: ISO/DIS 27548:2023.

2) Under preparation. Stage at the time of publication: ISO/ASTM DIS 52938-1:2023.

3.1
rework, verb
unplanned operation, or series of operations performed on a nonconforming part to make it conform to the requirements

Note 1 to entry: Rework of nonconforming parts should be performed by an approved process and does not require customer approval.

EXAMPLE Required hole in part is drilled too small. Part is reworked by drilling the hole to the specified width by the approved drill process.

3.2
repair, verb
operation, or series of operations performed to preserve or to restore the function of a defect part or product

Note 1 to entry: Repair of nonconforming parts require customer approval.

EXAMPLE Part is broken or damaged (e.g. dent in part or something broke off part), but the specified requirements can still be restored/preserved (e.g. dent is filled or the broken off piece is added/replaced).

3.3
reuse, verb
<of feedstock> supply and process *used feedstock* (3.4) in subsequent build cycles

Note 1 to entry: Reuse of feedstock such as powders or resins normally requires additional processing, such as sieving, or drying of powders or filtering of photopolymer resins.

Note 2 to entry: Reuse can include blending of different batches of feedstock, such as blending or used and virgin material, or blending of used material from different batches.

3.4
used feedstock
feedstock that has been supplied to an AM machine that has been subjected to at least one previous build cycle

3.5
additive system operations
operation of an entire additive system or any component of an additive manufacturing system

Note 1 to entry: Additive systems operations typically include data preparation, system set-up, build-cycle operation, feedstock management and process finalization.

Note 2 to entry: Additive system operations are illustrated in Figure 4.

3.6
process finalization
process steps which are an intrinsic portion of an AM process category but are not part of the build cycle

Note 1 to entry: Examples for process finalization, see 7.7.6

4 Overview of AM related processes

In order to ensure high quality within an industrial AM production site, all AM relevant processes (see Figure 1) shall be considered. In the following document, all processes shown in Figure 1 will be discussed in detail and corresponding requirements will be given.

A quality management system (e.g. ISO 9001, ISO/TS 22163, ISO 19443, EN 9100, ISO 13485, IATF 16949) should be in place when the AM part manufacturer applies this document.

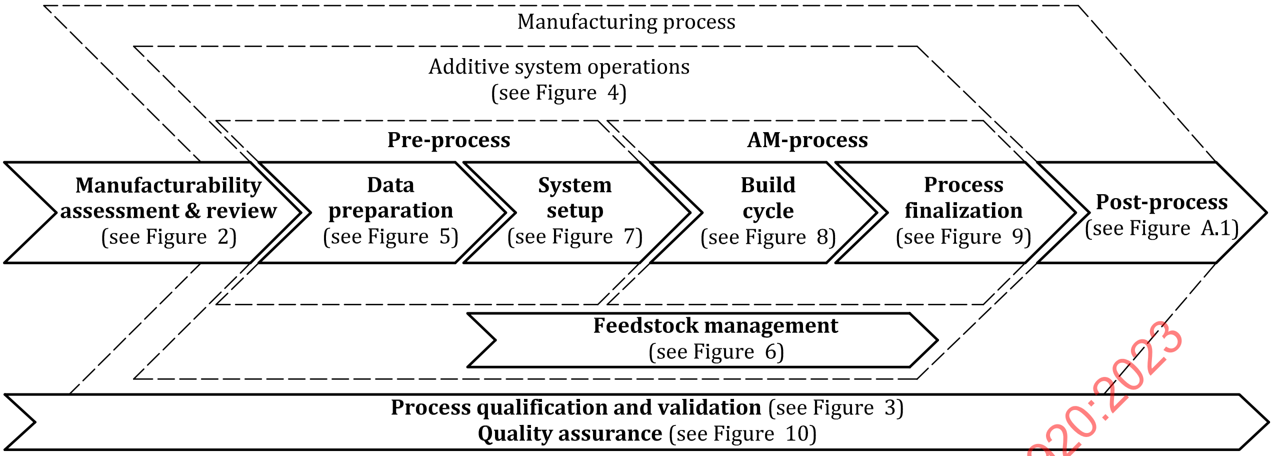


Figure 1 — Overview of AM relevant processes in an AM production site

5 Infrastructure of the part manufacturer

5.1 Environmental, health and safety (EHS)

Conformity to local statutory regulations regarding environmental, health and safety requirements shall be ensured. This includes explosion protection and personnel instruction concerning the occupational safety measures and equipment.

EXAMPLE Ventilation system appropriate for the processed materials; personal protective equipment.

5.2 Waste disposal

The categorisation into hazard levels of wear parts, waste feedstock and excessive material is recommended for appropriate disposal.

5.3 AM system installation

Utilities requirements (e.g. electricity, inert gases, ventilation) and operating conditions shall be collected, planned, and completed.

The specifications of the equipment manufacturer in respect to ambient and installation conditions shall be met. In case of deviation from the manufacturer's machine specifications, the reasons shall be documented.

NOTE When installing new machines, the conditions of already installed ones can be compromised.

Based on the requirements for the additive manufacturing technique, the installation conditions can comprise the following aspects:

a) logged installation conditions and qualification of the additive system;

b) logs covering all other quality-relevant influencing factors on the function of a system;

c) cleanliness of the production environment;

d) climate controlled rooms with controlled or permissible temperature, humidity, light conditions, air particle components;

e) extensive availability, minimum distance to neighbouring systems and equipment;

f) floor load capacity and evenness of the ground, absence of vibration;

g) no undesired sources that generate or extract heat in the vicinity;

h) no one-sided and/or local heating or cooling of the system;

i) absence of interference sources with high-frequency and electromagnetic radiation.

5.4 Ancillary equipment

Utilities requirements (e.g. electricity, inert gases, ventilation) and operating conditions shall be collected, planned, and completed. This includes all post processing equipment which affects product quality. This equipment can include, but is not limited to

a) sieving station, powder blender,

b) de-powdering system, blast cabinets, vibratory grinding machine,

c) band saw/wire cutting system,

d) UV oven, impregnation system, heating furnace, HIP furnace, and

e) testing and inspection equipment (e.g. calipers, scales, 3D-scanner).

5.5 Feedstock storage

The organization shall establish, maintain, and document the procedure necessary to ensure the feedstock quality. Temperature and humidity in a specified range shall be ensured.

5.6 IT infrastructure

The following aspects shall be fulfilled by the manufacturer:

a) security of the server landscape;

b) security of remote production survey systems;

c) maintenance of remote data access systems (e.g. see IEC 62443, ISO 27001);

d) provision of the IT hardware;

e) protection and archiving systems.

5.7 Foreign object debris (FOD)

Cleanliness of the equipment shall be maintained by the manufacturer:

a) All tools and operating media shall be as free from FOD as specified in the manufacturing plan (see 7.6.2).

b) Appropriate measures shall be taken to prevent cross-contamination of feedstock.

EXAMPLE Same machine operator works across several materials and working stations without proper procedures for changing/cleaning their PPE/clothing.

5.8 Provision of the process resources

The manufacturer shall ensure

a) uniquely marked tools (e.g. pliers, screws), and

b) sufficient operating media (compressed air, filter cascades, inert gas supply: temperature and purity, coolant, wearing parts, etc.).

EXAMPLE Allocation of a toolbox per material; inventories of disposable layer deposition systems.

5.9 Manufacturing management system

The manufacturer shall ensure that the correct steps occur in the qualified sequence with the corresponding parameters. This includes planning the machine capacity utilisation and available feedstock corresponding to a defined minimum level.

NOTE Efficient resource planning reduces machine downtime resulting in opportunity cost.

5.10 Maintenance/calibration system

The manufacturer shall maintain a system to document equipment preventative/predictive maintenance and calibration history.

6 Manufacturability assessment and review

6.1 General

The part manufacturer shall perform a manufacturability assessment and review.

Upon receipt of the customer order, the part manufacturer shall review the data from the customer to ensure all requirements, specifications, drawings and CAD models are clear and complete. Customer requirements can extend to production requirements such as heat treatment profile, build platform thickness, feedstock properties, batch purity or alternatively powder tests before build cycle.

This assessment and review include manufacturing feasibility. Any issues shall be reviewed with the customer/design authority for possible resolutions.

EXAMPLE Reference in the offer to part-unspecific material data sheet and standardised quality control.

Figure 2 shows the two individual steps for manufacturability assessment and review.

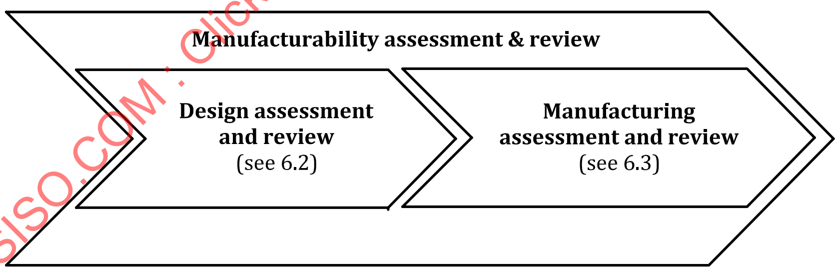


Figure 2 — Steps of manufacturability assessment and review

The assessment and review shall be performed by suitable personnel (see 8.2). It is important to include all part requirements.

6.2 Design assessment and review

The process-relevant design directives should be consulted to evaluate the manufacturing feasibility of the design. In addition, process-relevant manufacturing restrictions shall also be taken into consideration, such as minimum wall thicknesses and support accessibility.

EXAMPLE Aspect ratio of struts, holes, slits, gap size for joints or installation suitability of parts belonging together.

NOTE Further guidance is provided in ISO/ASTM 52910:2018, 6.8.

6.3 Manufacturing assessment and review

6.3.1 Additive manufacturing process

a) It shall be checked whether the desired part, including the part properties, can be manufactured with the machine/material combination. The process parameters for the machine / material combination will be qualified in 7.2.

EXAMPLE Minimum and maximum wall thicknesses within the desired part are compared to the qualified wall thickness range for the parameter set(s) for the selected material.

b) Check of dimensions/tolerances (see ISO/ASTM 52910:2018, 6.6): the tolerances specified in the design shall be attainable in the selected manufacturing process.

EXAMPLE Due to the process, fitting holes are not mapped. The required tolerances of holes are only attainable by further processing (drilling).

Thermal effects, such as cooling of the part or thermal post-treatment, can influence the part dimensions. This shall be considered before the start of the manufacturing process.

c) Check of material/material properties (see ISO/ASTM 52910:2018, 6.7): the manufacturing feasibility shall be considered beyond the selected technology, depending on the material over the entire manufacturing process. The specified material properties shall be incorporated here.

EXAMPLE 1 Ceramic-filled resins exhibit different manufacturing restrictions than pure photopolymers – even with the same AM machine.

EXAMPLE 2 Brittle materials (e.g. some titanium alloys) cannot sometimes be processed further mechanically.

Thermal effects, such as cooling of the part or thermal post-treatment, can influence the material properties. This shall be considered before the start of the manufacturing process.

6.3.2 Process finalization

It shall be checked whether the design is appropriate for process finalization operations required by the selected AM technology.

EXAMPLE 1 Check in advance concerning whether it is possible to remove raw material remaining after the process from internal cavities. A part can be suitable for additive manufacturing, but not useful for the intended application e.g. due to powder caking in cavities after heat treatment.

EXAMPLE 2 Multi-step process such as BJT of metals (described in ISO/ASTM 52900:2021 Annex B).

6.3.3 Post processing

If a further (semi-)automated manufacturing or inspection step occurs, it shall be checked whether the design is appropriate for this, if auxiliaries cannot be used.

EXAMPLE If machining is carried out to attain the required manufacturing tolerances, corresponding clamping points are to be provided as early as the data processing, if necessary.

7 Qualification of the additive system operations

7.1 General

The purpose of process qualification is to quantify the process location and dispersion parameters with regard to a certain property and thus ensure that the additive system operations can produce parts repeatable that meet specified requirements. Elements of process qualification and validation, as per ISO/ASTM TS 52930, are shown in Figure 3 and are briefly described.

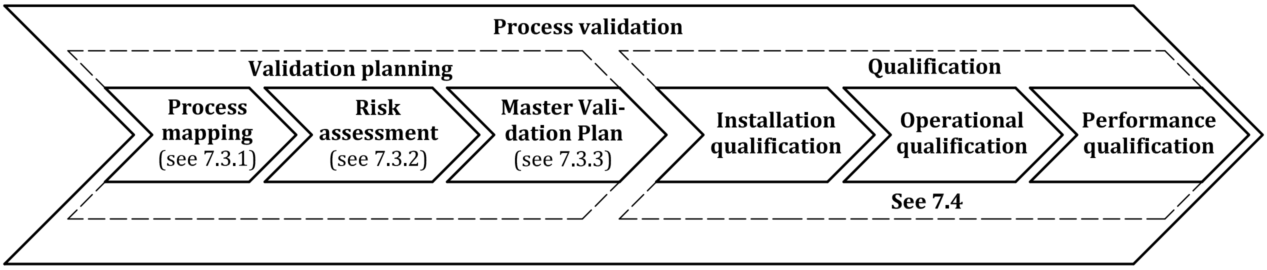


Figure 3 — Elements of process qualification and validation

7.2 Scope of qualification

Based on risk assessment, use-case or authority/regulatory requirements, the process qualification shall either be part-specific (process adjusted to part requirements), e.g. purpose of process clearance for serial production of a certain part, or process generic (parts adjusted to process performance), e.g. purpose of process clearance for production of changing parts of the same material.

Changes to the qualified additive system should be evaluated individually for the need of re-qualification depending on the quality impact to the process or the part (e.g. hardware, firmware, power source, machine repair, machine relocation, feedstock specifications). Where the evaluation concludes that the process or part is impacted by the change, a re-qualification shall be performed. Where there is no impact, re-qualification is not required. A record of the evaluation which includes changes in work procedures, parameter sets, evaluation method/s and the quality impact shall be retained by the organization. The master validation plan (see 7.3.3) shall list all cases when re-validation is required or not required.

NOTE 1 The phased approach of a qualification followed by production mode supports a flexible and cost-effective AM production for multiple applications. This also allows the concept of a direct inspection on a production run for yet unqualified values (e.g. one large part with many test artifacts to assess and ensure new material characteristics).

NOTE 2 Some industries refer to product specific as “build” qualification, which is encompassed in 6.3.

NOTE 3 Effort for (re)qualification can be reduced when changing one variable at a time: e.g. AM machine (same machine model), process parameter set (modification of a single variable), feedstock (same composition from a new supplier).

7.3 Validation planning

7.3.1 Process mapping

To ensure that all processes, interactions and influences are understood, a comprehensive process map should be created (e.g. as process flow chart, typically pictorially) showing the sequence of operations of the individual process steps and other relevant information.

7.3.2 Risk assessment

The method of risk assessment should be agreed upon between the part manufacturer and design authority prior to starting (e.g. with PFMEA or PFMECA as described in standards such as IEC 60812 or AS 13004). For general risk assessment, it can be referred to ISO 14971 and ISO 31000. Output of the risk assessment shall be used to define requirements for inspections according to AM part and AM process categories.

NOTE 1 There are currently plans to develop an AM process category specific risk evaluation standard. The current common practice is to use the system manufacturer documentation, industry best-practices and experiences.

NOTE 2 It is useful to document all relevant parameters and variables for each single process step. A helpful tool for this can be the turtle model, which helps to define the most relevant parts of the process [input, output, material and equipment, competence/skill/training, support processes/procedures and methods and key performance Indicators (KPI)].

7.3.3 Master validation plan

a) Validation plan: the part manufacturer shall define a validation plan for the series part. The pre-requisite is qualification of the material for a definite sequence of additive system operations (see 7.7). The plan shall contain the relevant test methods according to work instructions, procedural steps and/or other quality assurance elements. The part production is validated in a one, two or three stage process described in B.1 or ISO/ASTM 52901:2017, 4.5.1. Each stage is successfully completed upon signing by suitable personnel. The customer / design authority could request approval of the validation plan. The test methods can be applied to the parts themselves, associated production run values or co-built test artifacts.

   The methodical recording of the part requirements can be derived from different sources (e.g. ISO/ASTM 52901, ISO/ASTM 52904 or ISO/ASTM TS 52930). The inspection and test plan with defined limits to demonstrate fulfilment of part requirements can include requirements listed in ISO 17296-3:2014, 4.3. This makes it possible to derive which validations can be necessary beyond this document. Part marking can alter the validation effort if area, technique (during AM, laser engraving, labelling), indent or text size is not properly specified.

b) Execution of validation plan/report: the part manufacturer shall monitor and measure the part characteristics to verify that its requirements have been met. This shall be carried out at applicable stages of the manufacturing process in accordance with the validation plan that can contain application-specific instructions. The results of testing shall be documented in report(s). The customer/design authority could request approval of the validation report:

   1) Evidence of conformity to the acceptance criteria at each stage of the process shall be maintained. The identity of the person performing any inspection or testing and authorising release of part shall be recorded. As appropriate, records shall identify the test equipment used to perform measurement activities both during qualification and production.

   2) Part release and service delivery shall not proceed until the planned and documented validation report have been satisfactorily completed.

7.4 Qualification [installation, operation, and performance (IQ/OQ/PQ)]

a) Proof of evidence regarding compliance with the specified installation conditions shall be provided by corresponding documents (service report, final acceptance report, reports on modifications to the system, designation of the machine type including version status of the software components and, if applicable, version status of the hardware components, machine identification number). All quality-relevant system parameters shall be included in the documentation.

b) The process qualification forms the basis for both the identification of reproducible material properties as well as evaluation of the current process quality. This requires testing of reference samples, to a statistically significant extent, that includes all qualified process steps defined by the manufacturing plan.

c) The scope and frequency for controlling the process quality shall be defined and documented in the manufacturing process monitoring plan and records. Where required, co-built test artifacts serve the quantitative determination of material characteristics, for comparison to the control chart, as specified by the process qualification. Property specific tolerance bands, used for acceptance, are based on the value and dispersion parameters of the material characteristics, relative to positions in the build space. Pre-determined acceptance criteria shall be documented as specified by the OQ/PQ (e.g. control charts).

d) Equipment maintenance: Implementation of system-related maintenance and servicing activities by technical staff (see 8.2) including verification of expertise, depending on scope (daily/weekly/

monthly/quarterly/six monthly). All activities and changes shall be recorded in the machine life cycle document. The machine installation and maintenance refer to systems of the additive manufacturing process as well as post-processing equipment (e.g. sieving station, powder blender; de-powdering system, blast cabinets, vibratory grinding machine; band saw/wire cutting system, UV oven, impregnation system, heating furnace, HIP furnace, testing and inspection equipment).

NOTE IQ/OQ/PQ of PBF-LB equipment is described in ISO/ASTM TS 52930.

7.5 Manufacturing plan specification

The process steps of additive system operations as defined in 7.7.2 to 7.7.6 shall be specified including required verification measures and documentation. This typically includes:

NOTE An example of a manufacturing plan is described in ISO/ASTM 52904.

a) Parameter set: the process parameters selected for the qualification shall be defined, designated uniquely and documented. Changes to the process parameters require a re-qualification.

b) Feedstock testing: sampling with associated test methods shall be performed by the AM part manufacturer during the feedstock management.

c) Characteristic values/test artifacts: if characteristic values of the material are specified in relevant standards and/or other normative/regulatory documents, these characteristic values shall be determined with corresponding test methods.

d) Number of samples/production runs: the number of specimens and production runs shall be selected in a statistically relevant manner.

e) Positioning/alignment: the arrangement and orientation of the test artifacts shall be chosen appropriately corresponding to the circumstances of the AM machine and according to the application-specific requirements.

EXAMPLE It is not statistically representative to place all test artifacts within one laser field on a multi-laser machine.

f) Data communication: a qualification of the data processing shall be carried out in case of data transfer over several software programs.

EXAMPLE When generating the slice data over several interfaces, the qualification is based on a relevant and defined geometry.

g) Test methods: appropriate and validated destructive and non-destructive examination methods (e.g. ISO/ASTM 52927[3]).

h) Rework: in case of rework, a process for remedying part errors shall be documented.

EXAMPLE Machine oversized part; drill undersized hole; heat treatment for stress relief of warped parts.

NOTE The rejection path to allow for repair (e.g. weld up oversized hole) goes beyond this standard's scope.

Besides the above-mentioned aspects, there shall be a documented procedure detailing steps to follow when dealing with unscheduled interruptions, both during and after the qualification of the additive system operations (see 7.7.5.1).

3) Under preparation. Stage at the time of publication: ISO/ASTM DIS 52927:2023.

7.6 Documentation and tracing of the process steps

7.6.1 General

Documentation of the manufacturing process, its qualification and validation are required to verify quality assured processes and define the process qualification strategy. This documented information should be clear and easily understood. This can typically be achieved by elements such as language, style, pictograms, or ease of accessibility. The aspects described in 7.6.2, 7.6.3 and 7.6.4 shall be documented in a suitable way and contain the minimum information.

7.6.2 Manufacturing plan

All information of the individual processes shall be documented (e.g. job card system) to ensure quality assurance and traceability of the production steps. The manufacturing plan contains at least the following aspects:

a) Process sequence with its relevant processes and order of operation after the process mapping done beforehand (see 7.3.1).

   NOTE It can be used as simple example or as base for the more comprehensive process map.

b) Necessary documented information for each process. When carrying out relevant manual activity at the respective stations, steps that are prone to error and critical to quality and safety shall be emphasized, if applicable (e.g. standard operating procedure (SOP), work instruction (WI), procedures and process description).

   EXAMPLE 1 Cleaning the build chamber during system set-up.

   EXAMPLE 2 Documentation of the versioned, qualified machine parameters per executed build cycle.

c) Necessary qualification of personnel and their records for all relevant processes to ensure traceability who performed the qualification. Personnel requirements are defined in 8.2;

d) Traceability of test equipment used during manufacturing/qualification.

7.6.3 IQ documents

IQ documents for all manufacturing equipment and test equipment shall be provided. Each IQ document shall include at least the following (e.g. ISO/ASTM TS 52930 can be used for PBF-LB):

a) Documentation that the equipment was installed correctly and functions properly;

b) Calibration records (as applicable) to ensure traceability to calibration procedures and its history or certificate of the inspection equipment used for measuring and testing;

c) Maintenance plan and records for processes, procedures, and their intervals (including unscheduled). This includes but is not limited to:

   1) Regular measurement of the components with a direct influence on the additive manufacturing process (e.g. laser focus and laser power measurement, calibration of the feeding rates of the print head) in a manner and in intervals suitable for the application.

   2) Cleaning work shall be carried out in accordance with the maintenance plan. Maintenance and repair activities shall be carried out for the equipment type in use according to a procedure that has considered the equipment manufacturer's instructions for the inspection and maintenance as well as any other identified need for maintenance. This applies to both the frequency of the maintenance work to be carried out as well as the responsibilities for the necessary activities. Daily, weekly, and monthly maintenance and repair work shall be completed by the owner/operator of the equipment, whose implementation is to be verified in a suitable manner.

NOTE Changes in the additive system operation (see Clause 7) include modifications to the AM machine such as repair, machine software update, or moving thereof.

7.6.4 OQ/PQ documents for the complete process

OQ/PQ documents for the complete process can include but are not limited to the following:

a) proof of evidence regarding the quality of the feedstock;

b) instructions and records of feedstock management;

c) records of performed system set-up;

d) AM machine process data [e.g. build/error report(s)];

e) manufacturing specification for the co-built test artifacts;

f) manufacturing process monitoring plan and records to ensure the traceability of the characteristic values of each AM machine per build cycle, quality-relevant characteristics as well as test methods and intervals for monitoring these, detailed in respect to the individual process;

g) qualification measures for determining relevant input variables (e.g. feedstock properties) and resultant output variables (e.g. resulting value and dispersion parameters of mechanical properties), which are derived from defined, part-related indicators (see 7.1) along the additive system operation;

h) inspection and test results for reproducibility by analyses, e.g. regular monitoring of the error rates or process deviations pointing to a corrective measure (for possible effects see B.2).

7.7 Relevant process steps within the additive system operations

7.7.1 Overview of additive system operations

Unless otherwise required or approved by the organization, the requirements of the additive system operations (see 7.7.2 to 7.7.6), of the machine and of the personnel (see 8.2) shall be met according to Clause 8. The relevant elements of additive system operations are shown in Figure 4.

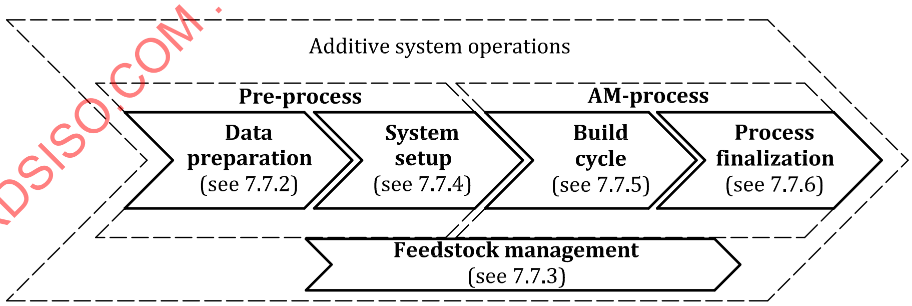
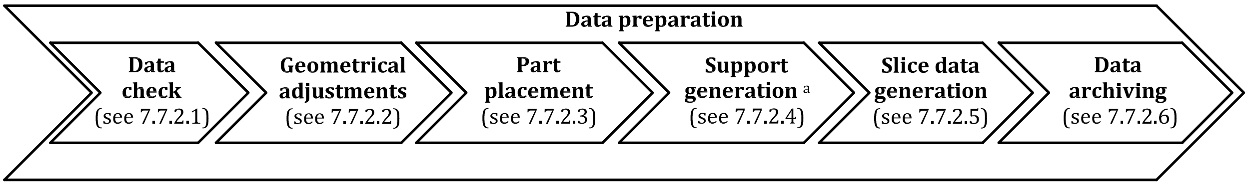


Figure 4 — Elements of additive system operations

NOTE For some technologies, feedstock management occurs only before the additive manufacturing process (e.g. MEX).

7.7.2 Requirements for pre-process: data preparation

Figure 5 shows the individual steps of the data preparation to be performed by the part manufacturer.



a Applicable depending upon selected technology.

Figure 5 — Steps of the data preparation

A uniform data and information structure according to ISO/ASTM 52950 shall be applied. If applicable, the process steps described in 7.7.2.1 to 7.7.2.6 shall be specified including verification and documentation as specified in the process qualification.

7.7.2.1 Data check

An inspection regarding error-free processability of the 3D data shall be carried out. If necessary, data fixing is carried out. If applicable, documentation of the conversion parameters from CAD, digital scanning software or other design creation software to STL, AMF, 3MF, STEP or another printable format is required.

EXAMPLE The checked data comprises software versions, configuration settings that directly impact resolution, size, and middle tolerances of the 3D data set.

7.7.2.2 Geometrical adjustments for manufacturing

Structural changes of the 3D data (allowances, cutting, hollowing, closure of holes, etc.) may be required for a manufacturing-compliant design (e.g. adequate post-processing). Considerations need to be given to the following three aspects:

a) Where required (e.g. by law, regulation, terms of delivery or customer specification) approval shall be obtained from the customer.

b) Traceability shall be maintained.

   EXAMPLE Digital part marking can be applied.

c) All adaptations shall be documented in comprehensible and verifiable form (this comprises versioning of the modified data set).

7.7.2.3 Part placement

Orientation and positioning of the single part as well as arrangement of all parts within the build envelope shall be considered with respect to the design and customer requirements, to individual manufacturing plans and to material behaviour.

EXAMPLE Material-specific characteristics comprise minimum part spacing, wall thickness, supporting area of the part or self-supporting angle.

7.7.2.4 Support generation

Where support structures are required, if these are not calculated fully automatically, a defined and user-independent workflow for the generation of supporting geometries shall be ensured.

7.7.2.5 Slice data generation

Conversion of the slice data with complete <build> process parameters (see parameter set in Clause 8) for the AM machine to be used.

a) In case of software updates, input and output data should be used to check that the generated data corresponds to a referenced output data.

b) The parameters for the data conversion shall be specified and complied within the corresponding procedure. If slice data is not calculated fully automatically, a defined and user-independent application of process parameters shall be ensured.

EXAMPLE Layer thickness.

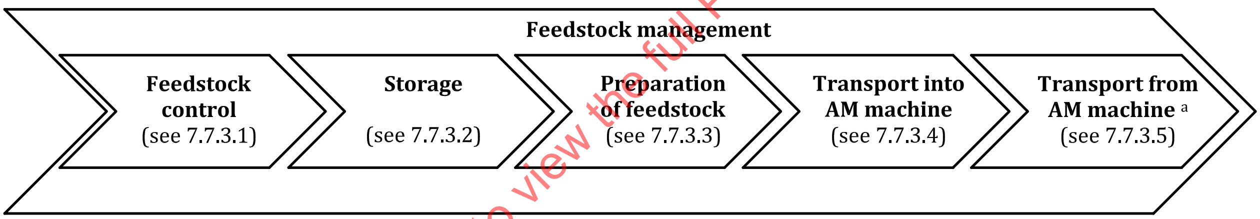
7.7.2.6 Data archiving

Unique, versioned archive of the digital files used for the build cycle shall be setup. The retention period according to the regulatory or application-specific requirements shall be recorded.

EXAMPLE 3D CAD files, drawings, build file, virtual support structure.

7.7.3 Requirements for feedstock management

Figure 6 shows the individual steps of feedstock management that shall be performed by the part manufacturer.



a Applicable depending upon selected feedstock state.

Figure 6 — Steps of feedstock management

Under feedstock control, a feedstock specification shall be established to ensure final part properties and suitability for the respective manufacturing process. In case of used feedstock, the part manufacturer shall define allowable limits for production. The feedstock supplier, as all suppliers, should be managed according to general quality management system requirements.

EXAMPLE 1 Chemical composition or alloying elements.

EXAMPLE 2 Degradation criteria include operating conditions, humidity, chemical by-products, organic compounds, biological agents.

When feedstock specifications are defined, the process specific, and application specific risks shall be considered. Depending on the feedstock and on the customer requirements, it is possible to establish a closed loop by re-supplying material in a controlled manner. To ensure the required properties of the feedstock (see ISO/ASTM 52928[4)] and ASTM F3049 for powder properties verification) relevant properties (depending on use-case, industry, and customer requirements) can be: chemical composition, contaminations, morphology, flowability and moisture), the following process steps shall be specified including verification and documentation as specified in the process qualification. The assessment process (see Clause 6) may have resulted in customer specific and/or application specific feedstock requirements.

4) Under preparation. Stage at the time of publication: ISO/ASTM DIS 52928:2023.

7.7.3.1 Feedstock control

The part manufacturer shall establish instructions to ensure that the feedstock meets the defined specification and is subsequently labelled to ensure traceability.

A material history record can be re-created for the material states in Table 1. Corresponding to the use, a unique relation between the finished part and used feedstock may be required.

EXAMPLE In a closed loop, some steps of the system set-up (see 7.7.4) can be carried out before feedstock control.

Table 1 — Traceability and batch purity

Lot use / Material use	Lot of feedstock	Batch of feedstock
Virgin feedstock (Filament, pellets, powder, liquid)	Clear allocation of the feedstock specifications to the part. Unique characteristics of the feedstock.	Limited allocation of the feedstock specifications to the part. Limited characteristics[a] of the feedstock.
Reused feedstock (Powder, liquid)	Moderate allocation of the feedstock specifications to the part. Limited characteristics[a] of the feedstock.	Difficult allocation of the feedstock specifications to the part. Limited characteristics[a] of the feedstock.

[a] Limited characteristics: key characteristics with specified allowable limits.

NOTE Low levels of traceability may not be suitable for all production components.

EXAMPLE Material, lot number. For metallic powders, see ISO/ASTM 52907

7.7.3.2 Storage

Necessary monitoring and control of storage climate (e.g. moisture level, temperature, or light source), with defined acceptable limits shall be provided. Specific storage requirements stated on the feedstock data sheet shall also be adhered to. The feedstock container may deviate from the original packaging but shall be compatible with the stored feedstock.

7.7.3.3 Preparation of feedstock (if applicable)

The following steps shall be part of the feedstock preparation but only for powders and liquids.

a) Sieving:

   1) supplied and sieved mass shall be recorded;

   2) mesh width shall be specified;

   3) sieve condition shall be specified and recorded;

   4) protective gas used shall be specified.

b) Blending: reuse of used feedstock which can be sieved beforehand and added to the virgin feedstock in a defined blending ratio. If different batches are blended with a different ratio, it shall be ensured that the feedstock specifications and traceability are still met.

   EXAMPLE Avoidance of cross-contamination, overpressure, cleaning schedule, conveying system.

c) Homogenising: procedure to achieve a homogeneous blend and, if needed, conclusive sampling.

7.7.3.4 Transport into AM machine

To avoid cross-contamination where preparation of the feedstock occurs outside the AM machine, transport and mount cartridges or powder containers in sealed form shall be provided. The contact with the environment shall be minimised or excluded. The material history shall be documented. This documentation includes supplied and removed amount to the build cycle as well as batch allocation.

7.7.3.5 Transport from AM machine (applicable for powder)

Unique marking of used feedstock is maintained for feedstock control until the next process step is determined to avoid cross-contamination.

7.7.4 Requirements for pre-process: system set-up

Figure 7 shows the individual steps of the system set-up to be performed by the part manufacturer.

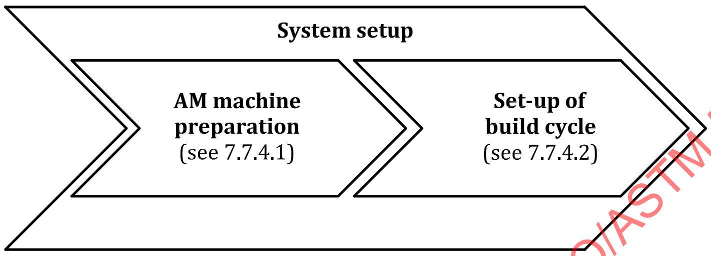


Figure 7 — Steps of the system setup

If technically applicable, the process steps described in 7.7.4.1 and 7.7.4.2 shall be specified including verification and documentation as specified in the process qualification.

7.7.4.1 AM machine preparation

Restoration of the initial machine state for the following build cycle:

a) Proper preparation of the machine by corresponding personnel (see 8.2). The preparatory steps indicated by the equipment manufacturer for the machine start shall be observed.

b) Cleaning processes shall be carried out according to equipment manufacturer procedures.

c) Filter state: applicable for PBF/M and DED techniques: Depending on the material and protective gas, the filter service life or filter type shall be allocated uniquely in order to ensure a reproducible build process and protective gas control.

   NOTE The potential pyrophoric nature of the dust on the media is considered when removing or replacing filters.

7.7.4.2 Set-up of build cycle

Several aspects shall be considered in terms of the build-cycle.

a) Build platform: based on the material type and factors such as shrinkage, a build platform with appropriate properties (e.g. size, thickness, or material type) shall be determined and specified.

b) Feedstock state (see Table 1) in the machine shall be specified.

   1) Sufficient feedstock (and if applicable support material, binder, and ink) for the build cycle shall be ensured.

   2) Existing feedstock shall meet feedstock specifications.

   3) Material container or material batch shall be identified and recorded.

      EXAMPLE In the PBF-LB/M technique in DIN 65124 or after acceptance by the equipment manufacturer

c) Depending on the requirements for the build cycle, a type and configuration of the layer deposition system shall be specified to ensure a reproducible layer deposition.

d) The part build program number and its revision shall be specified.

e) Choice of the protective gas and its requirements (e.g. purity, composition) depending on the material applicable for PBF/M and DED techniques shall be documented.

7.7.5 Requirements for additive manufacturing: build cycle

Figure 8 shows the individual steps of the build cycle to be performed by the part manufacturer.

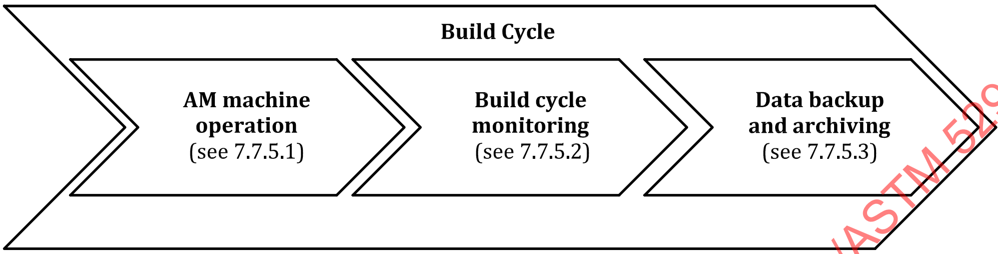


Figure 8 — Steps of the build cycle

If applicable, the process steps described in 7.7.5.1 to 7.7.5.3 shall be specified including verification and documentation as specified in the process qualification.

7.7.5.1 AM machine operation

The AM machine operation starts and executes the build cycle.

a) The AM machine shall be operated in accordance with the manufacturing plan (see Clause 8):

NOTE The manufacturing plan considers instructions provided by the AM equipment manufacturer and if needed, instructions for the AM process step. This includes application-specific work instructions.

1) quality data logs generated from the build cycle shall be recorded; engineering data logs generated from the build cycle should be recorded;

NOTE 1 Quality data: data that will be used to release or determine the quality impacting decisions.

NOTE 2 Engineering data: data that will be used to monitor the process performance indexes for future improvement and used as appropriate to direct and lead process improvement metrics.

2) data set from the manufacturing batch (geometry, number, layer thickness, infill pattern or hatching strategy);

3) process parameters (e.g. feed rate, nozzle cleaning steps, material supply or layer deposition, calibration, beam power, scanning rate, oxygen content, temperature curve, pressure gradient);

4) status of AM machine and ancillary equipment;

5) feedstock material (e.g. batch number) build platform material;

6) machine identification (e.g. serial number, build platform, type of protective gas);

7) interruptions with quantity and duration.

b) Interruption of the build process: Interruptions and procedure for restarting, that have been identified and approved during the qualification process, shall be defined in the instruction. Any other interruption shall be unplanned interruptions. Unplanned build process interruptions during the PBF machine build cycle shall be designated as a failed build on the manufacturing plan. All components of failed builds shall be rejected. Material review board (see ISO 9001) may accept rejected components that were not affected by the build interruption.

7.7.5.2 Build cycle monitoring

The actions to be taken for different feedback parameters (e.g. short-feeding, dosing) shall follow a procedure or work instruction. Automated AM process monitoring based on installed sensors can be used for quality assurance purposes if these are provided.

a) Recording and evaluation of the build cycle via imaging methods: the recorded data enable the analysis of errors or the tracing of part defects to process deviations.

b) Visual inspection of the material deposition: a layer error analysis (partially real-time-controlled) to detect an irregular feedstock distribution on the build surface [after each layer] can be integrated in the quality assurance.

c) Melt pool monitoring: Applicable for PBF/M and DED techniques: the complete joining of the material is monitored at the melt pool in which the process deviations are detected. This allows conclusions regarding potential part errors.

d) Energy power at the build field: Applicable for PBF, DED and VPP techniques: the energy power at the build field can be recorded with a measuring device decoupled from the laser or electron beam. This prevents interfering elements (e.g. effective absorption rates, laser protection window, smoulder formation) from being recorded.

NOTE 1 Monitoring the analysis of co-built test artifacts supports the decision of a production run's success, see 8.5.

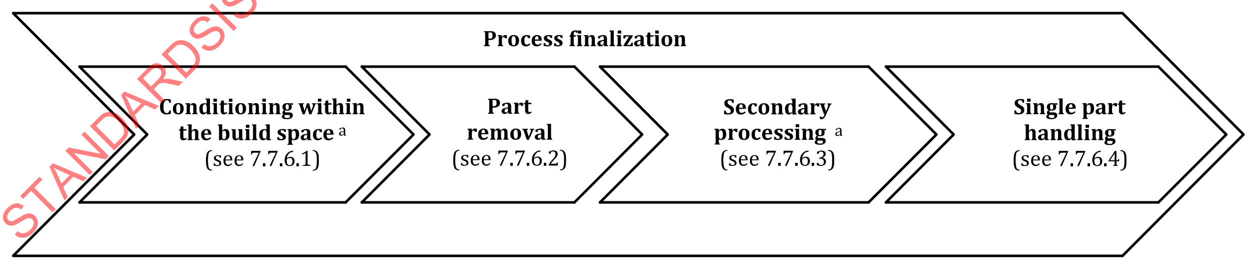
NOTE 2 In highly regulated industries, when very big or complex parts are being produced "In-process inspection" and "In-process rework" are potentially necessary as additional steps.

7.7.5.3 Data backup and archiving

All relevant recorded data shall be backed up at the appropriate interval and retained according to the regulatory or application-specific requirements.

7.7.6 Requirements for AM-process: process finalization

Figure 9 shows the individual subsequent steps to finalize the additive manufacturing process.



a Applicable for multi-step processes as defined in to ISO/ASTM 52900.

Figure 9 — Steps of the process finalization

The scope of the process finalization is derived from the selected AM technology and material. The methods and conditions of techniques for process finalization shall be standardized, where possible, and integrated in the qualification (see 7.3). If product specific process finalization techniques are necessary, these shall be documented. If technically applicable, the process steps described in 7.7.6.1 to

7.7.6.4 shall be specified and executed in a controlled manner, including verification and documentation as specified in the process qualification. The order in which these process steps are performed can change, depending on technology and organization.

7.7.6.1 Conditioning within the build space

If applicable, controlled acclimatisation within the build space shall be ensured. Build chamber conditioning can occur outside the AM machine.

EXAMPLE Cooling process with defined temperature curve, either in the build chamber or in specific conditioning stations.

7.7.6.2 Part removal

Removal of the as-built parts and, if applicable, the build platform from the build space.

NOTE The AM machine is cleaned up after part removal (see 7.7.4.1).

7.7.6.3 Secondary processing

Subsequent machine-dependent processing is required to attain the desired material properties:

a) Burning out the binder is relevant for BJT/M, possibly for MEX/M techniques: A suitable sintering process shall be selected for extensive/complete removal of the binding material.

b) Impregnation is relevant for BJT/M, possibly for MEX/M techniques: A suitable melt impregnation shall be selected for extensive/complete removal of the residual porosity.

c) Heat treatment is primarily relevant for sintering techniques: A suitable temperature and/or pressure profile, possibly combined with a protective gas or vacuum, shall be selected to obtain the specified mechanical and/or metallurgical properties. For BJT/M the same furnace may be used both for de-binding (item a) and sintering (item c) to reduce handling of the brown part (intermediatory part between green part and sintered part. e.g. binder was removed but part is not yet fully sintered).

d) UV curing is relevant for VPP: A suitable exposure shall be selected for extensive / complete curing of the parts.

Some single part handling (see 7.7.6.4) may be required before.

7.7.6.4 Single part handling

Some single part handling may be required before secondary processing (see 7.7.6.3). The suggested steps may not be in chronological order given a manufacturer's workflow. If applicable, the following operations are required to prepare single parts for post-processing:

a) feedstock recovery (as applicable), separation of the parts from the build platform or unpacking from the powder cake and sorting;

b) cleaning or de-powdering;

c) removal of the technology-specific auxiliary & sacrificial structures (e.g. support structures, sprue): If 3D data sets are required owing to automated mechanical post-processing, the procedure to attain the correct data format shall be specified;

EXAMPLE The process description/sequences envisages that a STEP format is always present at the data input, which is utilised for the mechanical post-processing.

d) defined process-specific part conditioning.

Annex A shall apply for the process finalization followed by allocation, proper interim packaging of the parts and, depending on application and customer requirements, post-processing.

8 Quality assurance

8.1 General

The individual elements of the quality assurance to be considered by the part manufacturer comprise personnel, documentation, infrastructure, and quality control as shown in Figure 10.

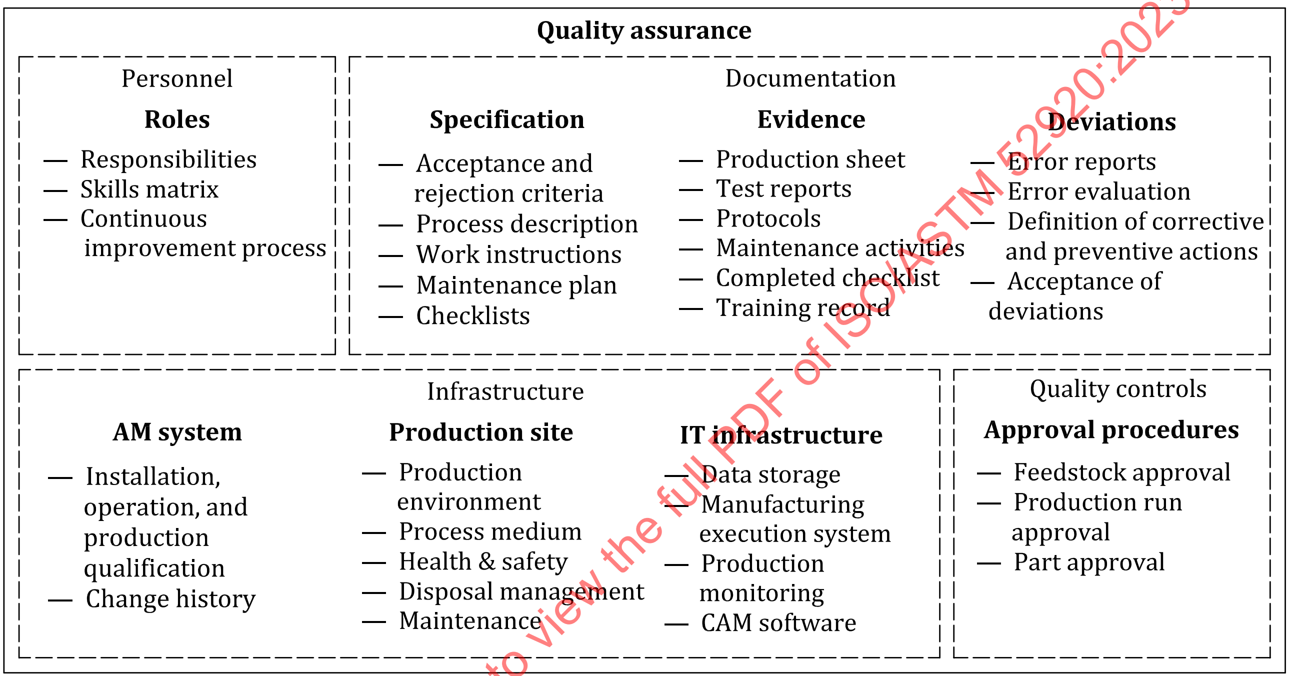


Figure 10 — Elemental parts and exemplary structure/clustering of quality assurance elements

8.2 Personnel requirements

Roles across the additive system operation and manufacturing processes (see Figure 1) shall be defined and personnel fulfilling these roles shall be qualified according to their tasks quality objectives, if applicable, according to existing standards. This qualification of personnel shall be documented and available for assessment. Each role should be conducted by suitable technical staff with demonstrable technological understanding. This includes knowledge about currently available AM standards, sound expertise of the relevant process category (according to ISO/ASTM 52900) and its quality assurance aspects. Typical personnel roles and responsibilities along the additive system operation are:

a) machine operator (for metal, see ISO/ASTM 52926-1 to ISO/ASTM 52926-5): the responsibilities are to manage feedstock (see 7.7.3) and carry out AM machine related activities (see 7.7.4, 7.7.5 and 7.7.6).

b) test personnel (for non-destructive testing, see ISO 9712).

c) quality engineer: the responsibilities include to check the maintenance of the systems, to perform process qualification, to check compliance to procedures and review the documentation (e.g. inspecting the required quality records in one or more randomly selected job audits).

d) AM coordinator (for metal, see ISO/ASTM 52935): Depending on the level, the responsibilities can include but are not limited to: verifying the part requirements, manufacturability assessment & review (see Clause 6), performing data preparation (see 7.7.2), implementing quality procedures, arranging the maintenance of the systems, implementation of and compliance with the work safety precautions, assessing and implementing manufacturing suitability, qualification, and documentation.

e) Maintenance personnel: The responsibilities are to carry out maintenance and repair operations as per machine manufacturer prescriptions and trainings, and to record maintenance history.

8.3 Non-conformities

8.3.1 General

The part manufacturer shall establish and maintain procedures to ensure the identification and segregation of all non-conforming materials, parts or work to prevent its use or shipment.

8.3.2 Acceptance criteria

To decide upon the success of a conducted step, typical deviations occurring in the additive system operations shall be approved and documented.

Acceptable technology-specific limits thereof shall be defined by suitable technical staff as part of the quality assurance aspects listed in 7.7.

A defined and referenced methodology for the individual control points shall be known and easily accessible to the personnel.

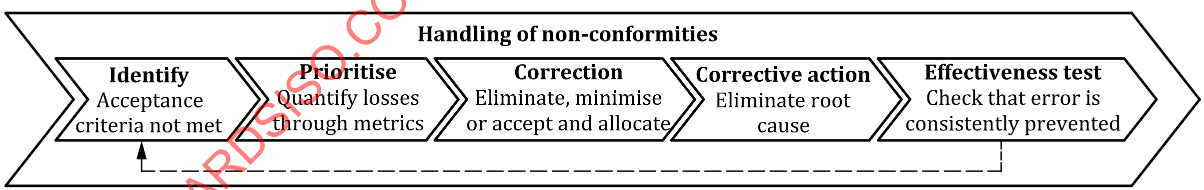
Various mediums can be used including writing, values, drawing, haptic or visual limit samples.

EXAMPLE 1 For data check: an error catalogue of critical geometries leading to build failure and/or compromised process finalization.

EXAMPLE 2 For system set-up: the permissible state of a component that directly impacts the build cycle.

8.3.3 Handling of non-conformities

The procedure, including developing a corrective and preventive action plan, shall be part of the quality management system. Figure 11 shows a possible systematic approach on how to handle non-conformities.



Key

– – ► control loop when corrective action is insufficient

Figure 11 — Handling of non-conformities

Control and quarantine of non-conformities shall be in accordance with the quality management system and customer requirements. All rework (see Clause 8), repair and an approved deviation shall follow a documented procedure which ensures that all aspects of the part requirements (see 6.2) are fulfilled. Depending on the application and customer requirements rework and repairs need to be approved by the customer.

EXAMPLE Identification and separate assessment of quarantined parts with a detected non-conformity.

Further details to the specific steps of handling non-conformities shown in Figure 11 are available in quality management standards like ISO 13485:2016, 8.3, 8.5.2, 8.5.3, EN 9100:2016, 8.7, 10.2 and ISO 9001:2015, 8.7, 10.2.

8.4 Continuous improvement process

The procedure shall be part of the quality management system and used by the personnel. Further details are available in ISO 13485:2016, 8.5.1, EN 9100:2016, 10.3 and ISO 9001:2015, 10.3.

NOTE Learning experience from non-conformities are used for training purposes.

For continuous improvement, root cause analysis using recommended methods shall be employed to determine the cause of process deviations leading to unsuccessful build and insufficient part quality and the results shall be documented in an appropriate manner.

EXAMPLE Methodologies to support sustainable improvement: customer satisfaction survey, 8D report, Ishikawa diagram, or process failure mode and effects analysis (PFMEA).

8.5 Quality controls

8.5.1 General

Figure 12 shows the possible individual steps of quality control.

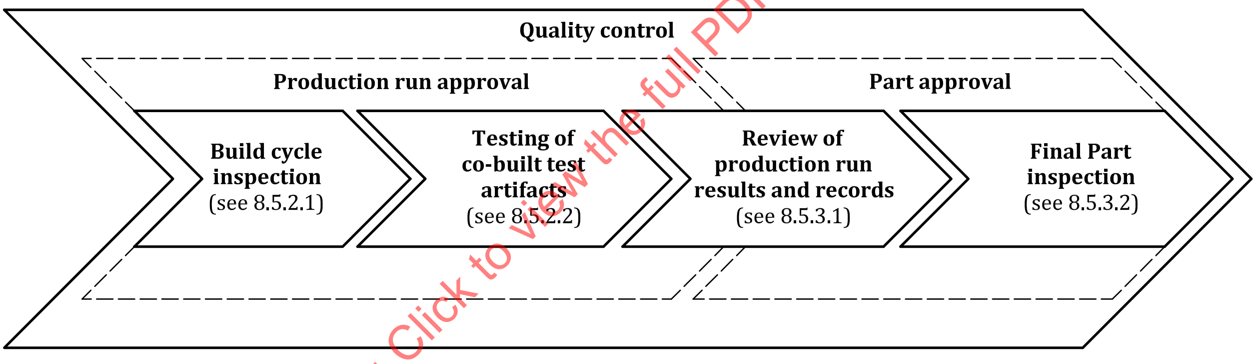


Figure 12 — Steps of quality control

Along the manufacturing process-relevant tests shall be conducted as specified in the manufacturing process monitoring plan (see 7.5 and 7.6).

The acceptance criteria for a production run shall be specified in the manufacturing plan (see 7.5 and 7.6.2) including all applicable tests and documentation of the test results.

NOTE This applies to a part/component, a material blank or a test artifact.

EXAMPLE Temperature gradient of the build chamber temperature of the extrusion head, layer records (before/after layer deposition), melt pool data, protective gas gradient.

Figure 13 shows detailed examples for quality control.

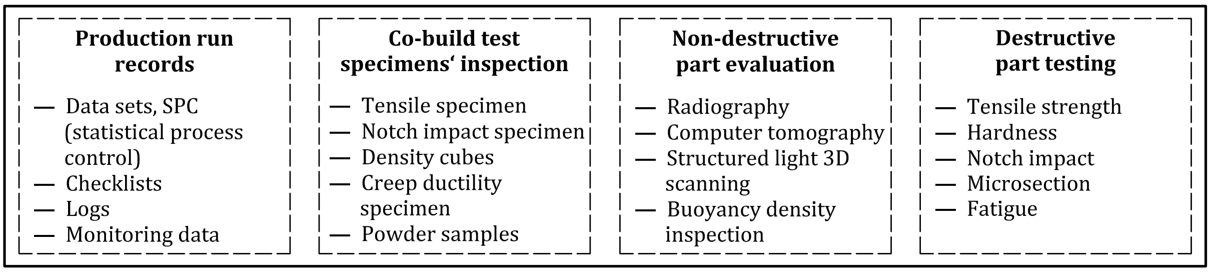


Figure 13 — Examples for quality control

Production run and part quality shall be verified by successful completion of the activities specified in the manufacturing plan, along with records that demonstrate compliance with the acceptance criteria specified in the manufacturing plan.

8.5.2 Production run approval

8.5.2.1 Build cycle inspection

Build cycle inspections shall be carried out as specified in the manufacturing plan (see 7.5) including visual inspections and review of available process logs, as required.

a) Visual inspection before and after part removal, in particular comparison with technique-specific errors (displacement, discolouration, defect, crack in the support, etc.) according to the specified quality characteristics or acceptance criteria, see 8.3 for handling of non-conformities.

b) The result of the visual inspection shall be documented. An error found during visual inspection can be documented in different ways, e.g. on a test report, a quality log, check list or a manufacturing plan record.

c) The visual aid for the visual inspection shall have a photographic reference or a physical sample. All visual aids should be inspected periodically to ensure the reference criteria are still met. The customer may set additional requirement for visual inspection, e. g., magnification factor, light source (intensity in lumen and temperature in K).

8.5.2.2 Testing of co-built test artifacts

Continuous testing of co-built test artifacts shall be used to demonstrate statistical control of material properties of the production run, in accordance with those specified by the process qualification (see 7.4).

NOTE Typical material properties include but are not limited to chemical composition, density, porosity, hardness, and static strength.

Retention of test artifacts and/or samples may be required. They can allow for unique traceability per production run if further destructive (e.g. static / dynamic load) and non-destructive (e.g. CT, X-ray, ultrasonic) tests must be carried out to gain additional insights (see ISO/ASTM TR 52905[5)]). Retention samples, including the associated documentation, shall be archived according to the regulatory or application-specific requirements. Retention samples can be copies of the produced parts or co-built test artifacts. Depending on the build height, several samples can be distributed in the entire build volume so that all layers of the build cycle are recorded by the inspection.

Depending on the regulatory or application-specific requirements, the density, porosity, hardness, tensile strength, notched impact strength (see ISO/ASTM 52908[6)]), and dimensional accuracy (see

5) Under preparation. Stage at the time of publication: ISO/ASTM DTR 52905:2023.

6) Under preparation. Stage at the time of publication: ISO/ASTM DIS 52908:2023.

ISO/ASTM 52902) should be monitored according to the manufacturing process monitoring plan (see 7.4).

8.5.3 Part approval

8.5.3.1 Review of production run results and records

After all tests were performed a review of all production run results and records shall be conducted to determine if the values are within the permissible range defined in the manufacturing plan. If so, the production run can be approved.

This comparison forms the basis for measuring the process quality and expected part quality. If the results are outside the specified intervention and warning limits, the production run is first regarded as rejected (see 8.3). Depending on the impact of the deviation, it shall be assessed whether the customer should be informed. Such a deviation shall also be documented (e.g. in the fault log). For further information see Figure B.2.

8.5.3.2 Final part inspection

Final parts are either approved according to predefined (internal) acceptance criteria or criteria specified in the purchase order (e.g. after ISO/ASTM 52901) and by agreement with the customer (e.g. in case of deviations).

Parts that do not adhere to the specification shall be marked accordingly. If the non-conformity cannot be accepted, reworked or repaired (see 8.3.3 and Figure B.2), the part shall be disposed of in the appropriate manner (e.g. in accordance with EHS, customer or regulatory requirements).

NOTE This document examines the process testing exclusively, whereby a basic pre-requisite for a random sample inspection of series parts is represented. An example overview of the separate, individual and/or random testing is presented in A.2.

Annex A
(informative)

Requirements for Post-processing and part approval

A.1 Post-processing

This subclause serves an allocation of the possible manufacturing and/or testing processes involved upon completion of the additive system operations. The methods normally applied in the post processing including shipment are largely standardised specifically. The corresponding normative documents to the post-processing methods used (for examples see Figure A.1) are applicable.

As a result, this document can therefore be used as a basis for the additive system operation and extended with any qualification standard for subsequent manufacturing steps. Quality assurance shall be implemented over the entire manufacturing process.

Figure A.1 shows the possible individual steps of post-processing required beyond the selected process finalization. Depending on the application, additional post-processing steps or a different order of steps can be necessary.

Post-processing shall have the following minimum documentation:

a) manufacturing plan;

b) process descriptions/sequences and work instructions for the relevant post-processing operations;

c) documentation of the personnel qualifications.

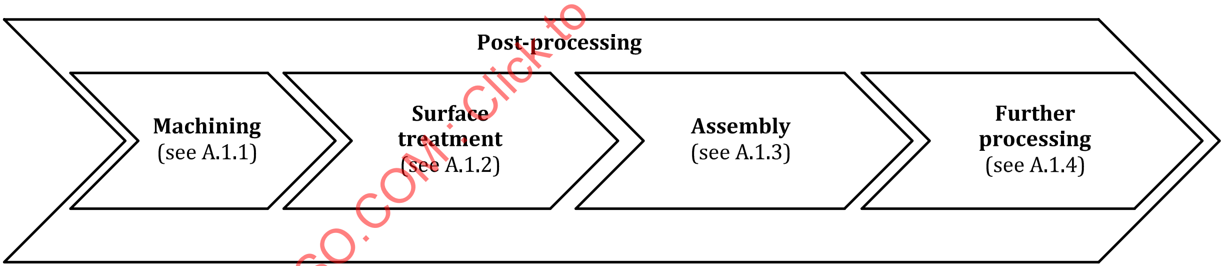


Figure A.1 — Steps of post-processing

The post-processing operations are required by parts specifications but cannot be attained with the selected additive manufacturing technology:

a) machining, e.g. milling, turning, drilling, abrasive slurries, (including cleaning, as required);

b) surface treatment, e.g. dyeing, painting, galvanising, ionization, shot peening, shot blasting, polishing, grinding, vibratory grinding, plating;

c) assembly, e.g. adhesive bonding, welding, thread insert);

d) further processing, e.g. cleaning, packaging, coating, sterilization).

A.2 Testing (separate, individual, or random sample testing)

The following options for testing exist:

a) Inspection for dimensional accuracy: use an appropriate method/s such as caliper, micrometer, CMM, optical, plug connection with counterpart, tactile, CT scan;

b) Destructive Testing: Mechanical and metallurgical properties. e.g. tensile, flexure, fracture, compression;

c) Non-destructive testing: e.g. CT scanning, x-ray, surface profilometer, hardness testing, proof testing.

NOTE 1 Process monitoring data is used for part approval, if validated.

NOTE 2 Chemical and thermal analysis are either non-destructive or destructive test methods.

NOTE 3 For main characteristics and test methods see ISO/ASTM 52927.

Annex B
(informative)

Supplementary information

B.1 Example of part specific qualification

The number of iterations varies depending on the complexity of the geometry and/or part requirements. Several phases (see Figure B.1) can be completed simultaneously.

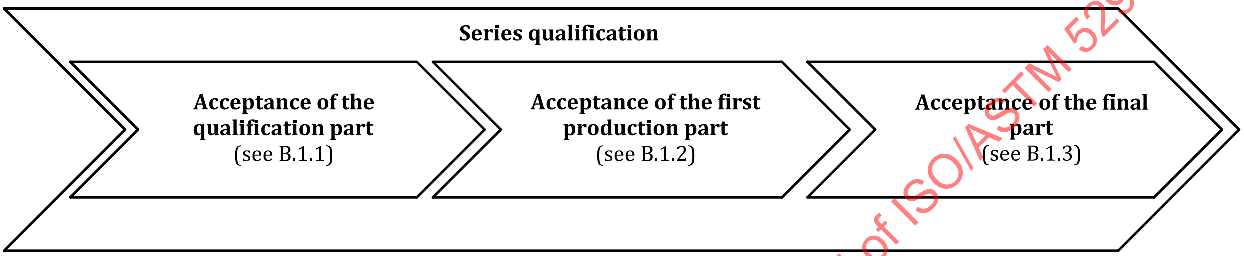


Figure B.1 — Phases of series qualification

B.1.1 Acceptance of the qualification part

Part-specific quality criteria extend beyond the qualified characteristic values, which are to be inspected. These comprise digital data processing (see 7.7.2; orientation, support), selection of the co-built test artifacts and the associated test equipment, definition of acceptance and rejection criteria, as well as post-processing.

If dynamic characteristics are available, but these have been determined without post heat treatment, they should be verified again in case of a manufacturing process that envisages this treatment.

If the size of the available installation space is not sufficient, if an orientation of the part is specified, the separate process steps should be validated: (digital) division of the geometry and (physical) jointing of the of the subcomponents, if permissible.

B.1.2 Acceptance of the first production part

Part-specific quality criteria should be validated in the final configuration. These criteria comprise digital data processing (see 7.7.2; positioning, arrangement), number of random samples, batch size of the co-built test artifacts and post-processing. Depending on insights, work instructions are supplemented, and limit sample parts produced for future evaluation (see A.1).

If a test setup has been operated to check the manufacturing feasibility, a new, compact setup can have a different effect on the validity of the test artifacts. Automated post-processing (blasting, heat treatment) in particular is highly dependent on the setup.

B.1.3 Acceptance of the final part

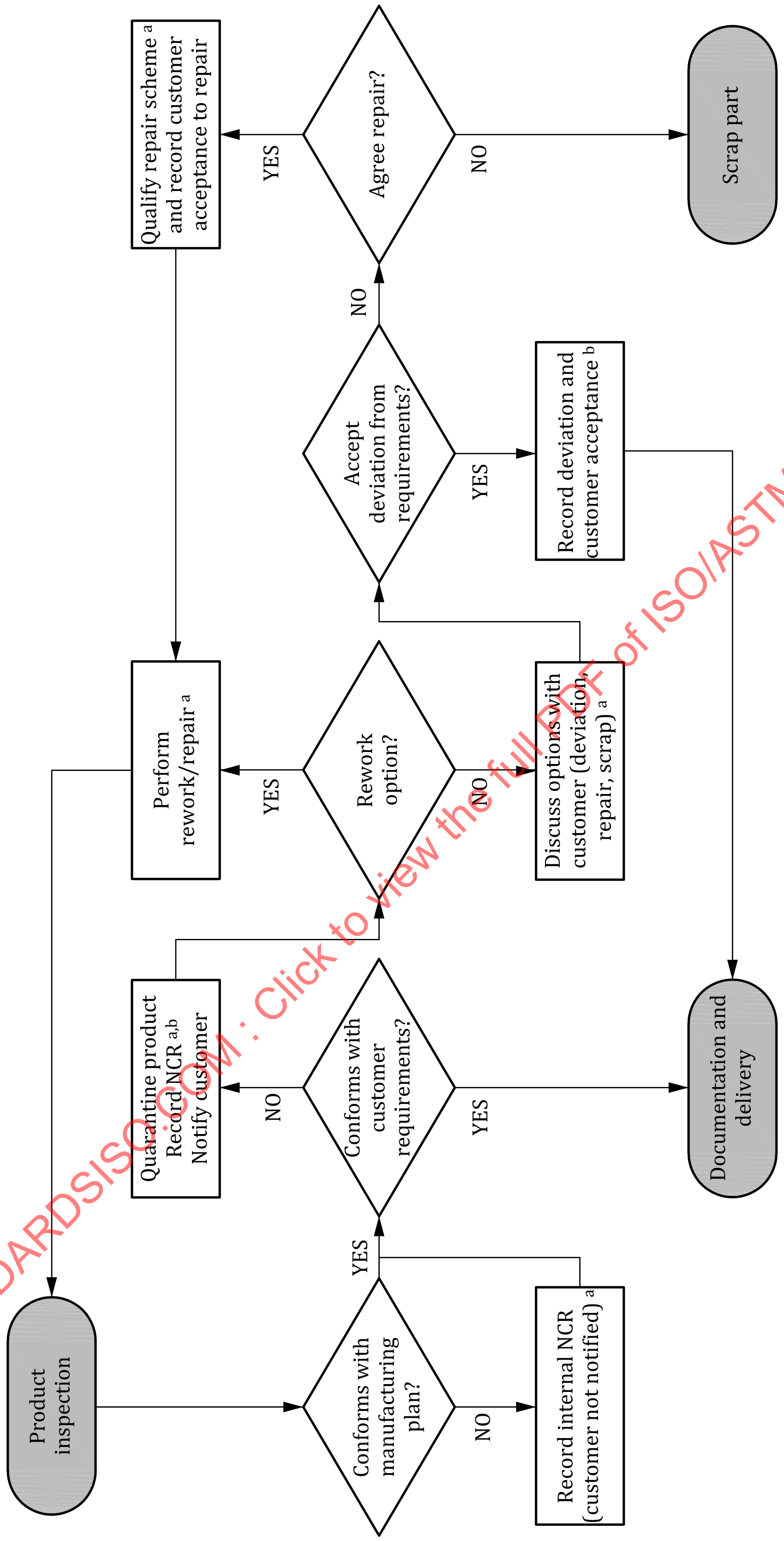
Part-specific process conditions should be documented continuously in production according to the validation plan (see Annex A). If the results are not consistent beyond several production batches or not within the part requirements, the qualification plan should be revised.

B.2 Notes on potential process deviations across AM technologies

B.2.1 General

The search for the cause of the error is difficult owing to the many influencing factors. A rigorous categorisation of the error records is therefore recommended.

Figure B.2 illustrates a possible process on how to handle non-conforming products.



a Used for determining corrective actions.

b Used for determining preventative actions.

Figure B.2 — Systematic approach to loss reduction encompassing all aspects of production

B.2.2 Examples across AM technologies

This subclause gives examples specific to some of the AM technologies and are applicable wherever cells are shaded. For an enhanced overview, a reference to the main body is listed in italic. Table B.1 does not claim completeness and may be incrementally increased.

Table B.1 — Subclause specific process deviation examples for some of the AM technologies

Subclause specific examples for some of the AM technologies	AM/Polymer					AM/Metal		
	MEX	VPP	MJT	BJT	PBF	PBF	DED	BJT
7.7.2.2, 7.7.2.3, 7.7.2.4— process simulation process simulation can be used to increase process predictability, thus avoiding build failure by optimising supports and part orientation. It can also serve to modify (digital) part geometry as to compensate for displacements due to thermal stresses. The validation plan should include process simulation when applying a pre-deformation to a part.						■	■	
7.7.2.5 b) — process parameters Z-compensation and scaling to compensate for geometrical and process-dependent shrinkage or warpage can be included in the validation plan	■	■		■	■		■	■
7.7.2.5 b) — process parameters build chamber temperature	■				■	■	■	
7.7.2.5 b) — process parameters speed of the layer deposition system		■	■	■	■	■	■	■
7.7.2.5 b) — process parameters deposition rates, travel paths, fill density	■		■	■			■	■
7.7.2.5 b) — process parameters beam exposure strategy, beam speed, beam power					■	■	■	
6.3.1 c)— feedstock specification geometrical specifications of the filament	■						■	
6.3.1 c) — feedstock specification particle size distribution, particle form NOTE A standardised specification is used (e.g. ASTM F3184).				■	■	■	■	■
6.3.1 c), 7.7.3.1 — feedstock control consumed and newly added mass, blending ratio new vs. used powder (refresh rate), angle of repose, moisture content				■	■	■	■	■
6.3.1 c), 7.7.3.1 — batch control filament diameter, moisture content	■						■	
6.3.1 c) 7.7.3.1 — feedstock samples retain feedstock samples and check according to the frequency defined in that facility procedure.				■	■	■	■	■

Table B.1 *(continued)*

Subclause specific examples for some of the AM technologies	AM/Polymer					AM/Metal		
	MEX	VPP	MJT	BJT	PBF	PBF	DED	BJT
6.3.1 c); 7.7.3.1, Table 1— limited characteristics limited characteristics can have minor permissible variation from the specification as per the material certificate provided by the feedstock supplier. Degradation criteria include carbon or oxygen level, particle size distribution NOTE For metal powders, the purchase specification (e.g. tested according to ISO/ASTM 52907) typically has tighter requirements than the use specification to accommodate for degradation in properties as the powder is reused.						■	■	
7.7.4.1 a)— machine preparation optics, support for build platform, material container, disposal of residues in the build chamber, complete emptying of the overflow bin				■	■	■		■
7.7.4.1 b) — cleaning pyrometer check, layer deposition system's orientation, layer deposition system's state or change per manufacturing batch					■	■		
7.7.4.1 b) — cleaning inspection of the extrusion nozzle	■						■	
7.7.4.2 a) — build platform material (compatibility with temperature and feedstock), cleanliness, surface quality, thickness, flatness/waviness	■	■	■	■	■	■	■	■
7.7.4.2 c) — layer deposition system choice of system (roller, brush, soft or hard lip) depending on the powder, liquid or part geometry		■		■	■	■		■
7.7.4.2 b) 2)— undamaged feedstock resin does not contain solid particles, sealed container		■	■					
7.7.4.2 b) 2) — undamaged feedstock powder does not contain contamination				■	■	■	■	■
7.7.5.1 a) 3) — process parameters incorrect setting of process parameters can lead to part failures: cracking, delamination, high residual stresses, poor surface finish, increased part porosity, lack of fusion, polymerisation, bonding or sintering	■	■	■	■	■	■	■	■
7.7.6.2 — part appearance poor dimensional accuracy, deformation, displacement, shrinkage, striation, undulation, sorting edges, discolouration, surface errors, down-skin errors, step formation, pore formation, oxygen embrittlement	■	■	■	■	■	■	■	■
7.7.6.2, 7.7.6.4 c) — support appearance Outline of the support structure (inside/to the part/to the build platform), strength of the support structure	■	■	■			■		
7.7.6 — effects in the build space unevenness of the build platform, too high temperature gradient (e.g. due to the packing density) within a build area	■			■	■	■		■