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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

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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).

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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.

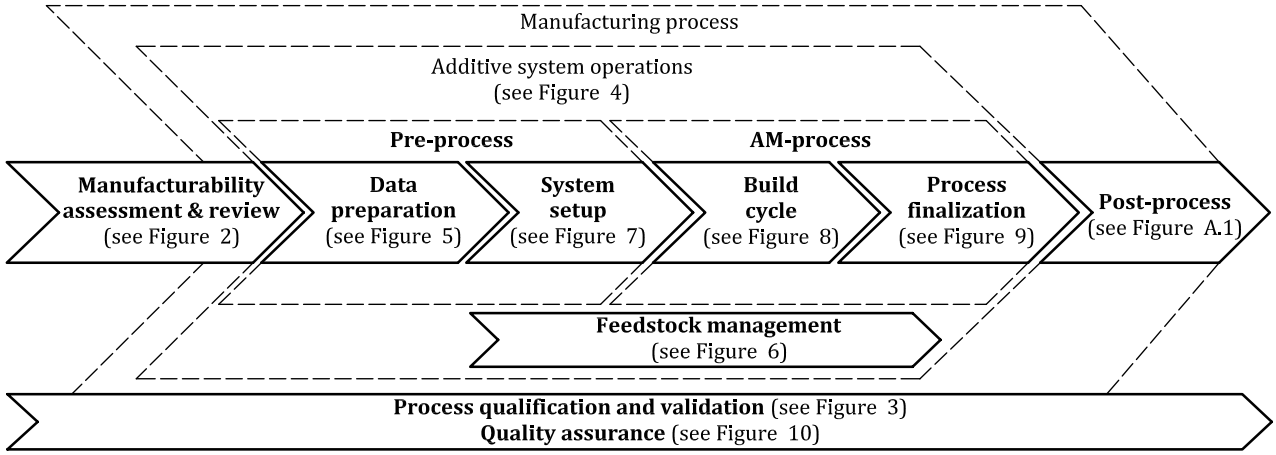

Figure 1 — Overview of AM relevant processes in an AM production site

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.

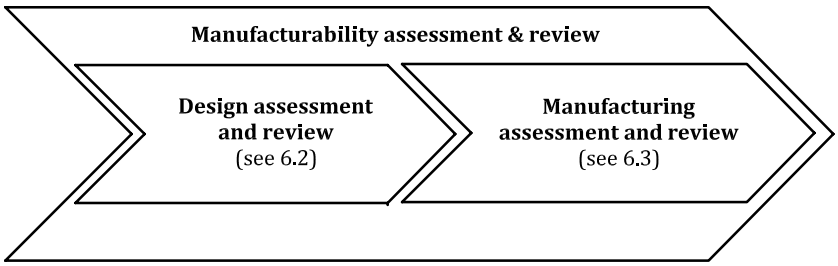

Figure 2 — Steps of manufacturability assessment and review

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.

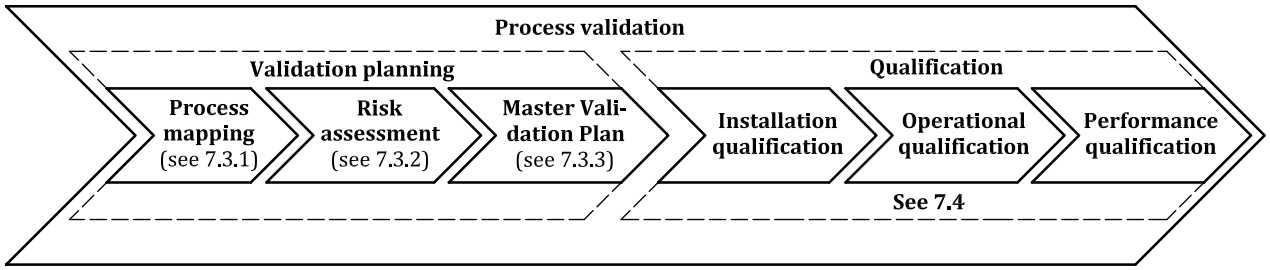

Figure 3 — Elements of process qualification and validation

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.