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Additive manufacturing - Qualification principles - Part 2: Requirements for industrial additive manufacturing sites (ISO/ASTM DIS 52920:2021)

Additive Fertigung - Qualifikationsprinzipien - Anforderungen an Standorte für industrielle additive Fertigung (ISO/ASTM DIS 52920:2021)

Fabrication additive - Principes de qualification - Exigences pour les sites de fabrication additive industrielle (ISO/ASTM DIS 52920:2021)

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Additive manufacturing — Qualification principles — Requirements for industrial additive manufacturing sites —

Part :
Requirements for industrial additive manufacturing sites

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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.

The committee responsible for this document is 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.

Introduction

Additive manufacturing increasingly represents an attractive alternative to established manufacturing methods 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 industrially (automotive, mechanical engineering, railway, aerospace, processing plants, medical, etc.). The present lack of standards means that processes for the manufacturing of parts need to be defined from scratch for each individual 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 shall be verified that these meet the requirements placed on them. To this end, the process chain and environment shall be designed in a way that the process quality and resultant 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 additively manufactured parts. 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 subprocesses 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 sites —

Part :
Requirements for industrial additive manufacturing sites

1 Scope

This document specifies the requirements, which are independent of the material and manufacturing method used, for part manufacturers using additive manufacturing techniques.

This document specifies criteria for additive manufacturing processes as well as quality-relevant characteristics and factors along the process chain 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 in this standard. The corresponding content is addressed in the equipment manufacturer guidelines and ISO/ASTM 52931, ISO/ASTM 52932, ISO/ASTM 52933, ISO/ASTM 52934 and ISO/ASTM 52938-1[1)].

A quality management system (e.g. ISO 9001, ISO/TS 22163, ISO 19443, SAE AS 9100D, ISO 13485, IATF 16949) should be in place when the AM part manufacturer applies this standard. Additionally, this standard 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 — Terminology*

ISO/ASTM 52901, *Additive manufacturing — General principles — Requirements for purchased AM parts*

ISO/ASTM 52902, *Additive manufacturing — Test artifacts — Geometric capability assessment of additive manufacturing systems*

ISO/ASTM 52910, *Additive manufacturing — Design — Requirements, guidelines and recommendations*

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

ISO 9001:2015, *Quality management systems — Requirements*

ISO 9100:2016, *Quality Management Systems — Requirements for Aviation, Space and Defence Organizations*

ISO 13485:2016, *Medical devices — Quality management systems — Requirements for regulatory purposes*

1) Work in progress – not published yet.

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/

3.1
rework
unplanned approved process of performing a task that brings the part back into specification

3.2
used feedstock
recycled feedstock
feedstock that has been supplied to an AM machine during at least one previous build cycle

4 Qualification of the additive system operations

4.1 Quality-relevant process steps within the manufacturing process

The requirements of the additive system operations (4.2 to 4.6) and of the personnel (5.2) shall be met.

The relevant areas of the process chain are shown in Figure 1. All terms shown in figures are underlined throughout the document. This comprises:

1) quality assurance: activities performed throughout the entire process chain that focus on providing confidence that the part quality will satisfy the specified requirements and ensure production traceability;

2) verification of part requirements: activities to establish clear, well-defined and measurable physical and chemical characteristics upon which part acceptance or rejection is specified;

3) data preparation: digital activities on the as-designed part occurring before the additive manufacturing process;

4) feedstock management: material flows occurring within the additive system operations;

   NOTE Feedstock management occurs before the additive manufacturing process only for some technologies (e.g. MEX)

   a) system set-up: feedstock loading;

   b) build cycle: feedstock availability and consumption;

   c) default post-processing: feedstock recovery for intended reconditioning and reuse;

5) system set-up: manual activities occurring in the immediate environment of the additive system and serving to initiate the additive manufacturing process;

6) additive manufacturing process: build cycle in which parts are produced additively;

7) default post-processing: activities on the as-built part occurring in the environment of the additive system and performed downstream of the additive manufacturing process;

8) end processing: activities on the near net shape part occurring outside the immediate environment of the additive system, after the additive system operations (see Annex A).

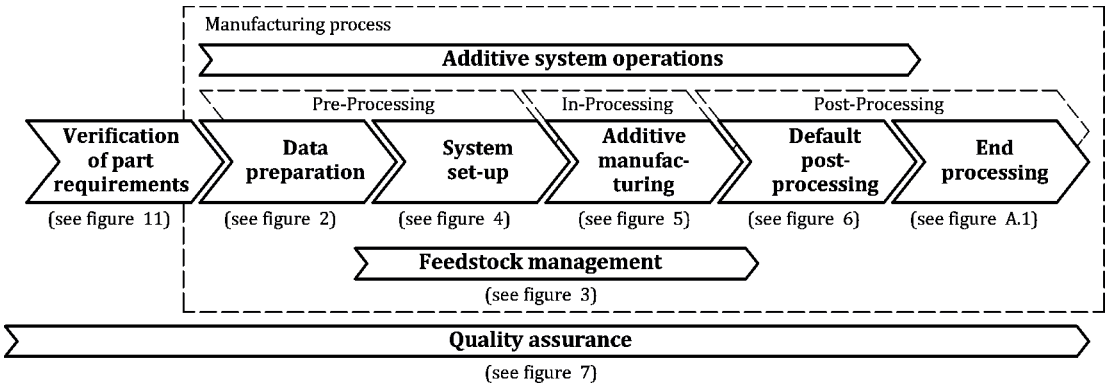

Figure 1 — Quality ensured process in an additive manufacturing production site

Quality assurance requires a comprehensive specification of the manufacturing process and defined part requirements (Figure 1).

4.2 Requirements for pre-processing: data preparation

Figure 2 shows the individual steps of the data preparation to be performed by the part manufacturer.

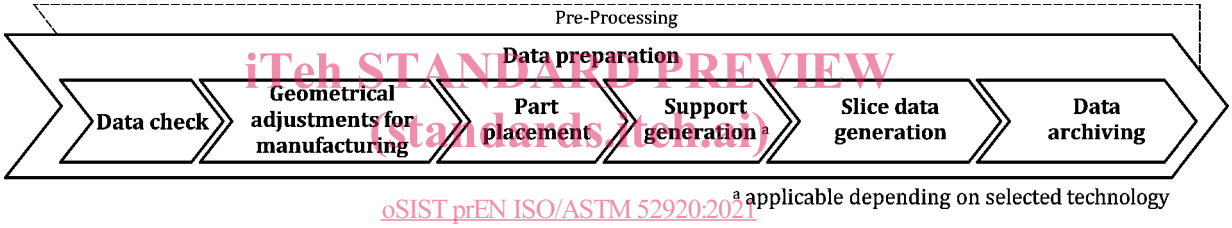

Figure 2 — Elements of the data preparation

A uniform data and information structure according to ISO/ASTM 52950 shall be applied.

If technically applicable, the following process steps shall be specified including verification and documentation as specified in the process qualification:

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 or AMF is required;

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

2) geometrical adjustments for manufacturing: allowances, cutting, hollowing, closure of holes, etc.; structural changes of the 3D data may be required for a manufacturing-compliant design (e.g. adequate end processing). Considerations need to be given to the following:

   a) approval may need to 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).

3) part placement: orientation, positioning of the single part as well as arrangement of all parts within the build envelope, with consideration of individual manufacturing plans and of material behaviour;

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

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;

5) slice data generation: conversion of the slice data with complete <build> process parameters (see parameter set in 4.8.3) 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 with in the corresponding procedure. If slice data are not calculated fully automatically, a defined and user-independent application of process parameters shall be ensured;

   EXAMPLE Layer thickness

6) data archiving: unique, versioned archive of the digital files used for the build cycle. Record retention period according to the regulatory or application-specific requirements.

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

4.3 Requirements for pre-processing: feedstock management

Figure 3 shows the individual steps for the feedstock management to be performed by the part manufacturer.

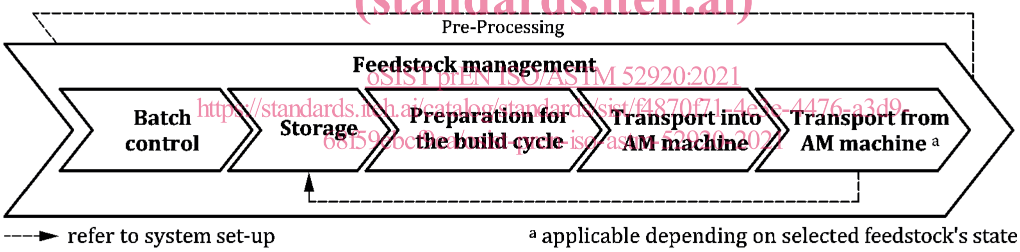

Figure 3 — Elements of the feedstock management

A feedstock specification is required to ensure its 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 Chemical composition or alloying elements

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

Depending on the feedstock and on the customer requirements, it is possible to establish a closed loop by resupplying material in a controlled manner. To ensure the required properties of the feedstock (refer to ISO/ASTM 52928 for powders), the following process steps shall be specified including verification and documentation as specified in the process qualification:

1) batch control: the part manufacturer shall establish instructions to ensure 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 4.4) may be carried out before item 1.

Table 1 — Traceability, iteration of recycling, batch purity

Lot use Material use	Batch from an individual lot	Batch from more than one lot
New feedstock (Filament, pellets, powder, liquid)	Clear allocation to the lot; Unique characteristics of the feedstock	Limited allocation to the lots; Limited characteristicsa of the feedstock
Used feedstock (Powder, liquid)	Clear allocation to the lot; Limited characteristicsa of the feedstock	Difficult allocation to the lots; Limited characteristicsa of the feedstock
[a] Limited characteristics: key characteristics with specified allowable limits.		

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

2) storage: monitoring and control of storage climate (in particular moisture, temperature or light source), with defined acceptable limits. 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.

3) preparation for the build cycle: if applicable, adaptation of the feedstock for the build cycle:

   a) sieving – only applicable for powder and liquids: supplied and sieved mass, mesh width, sieve condition, protective gas used;

   b) blending – only applicable for powder and liquids: 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 together 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) homogenizing – only applicable for powder and liquids: procedures to achieve a homogeneous blend and, if needed, conclusive sampling;

4) transport into AM machine: to avoid cross-contamination where step 3 occurs outside the AM machine, transport and mount cartridges or powder containers in sealed form. Minimise or exclude contact with the environment. The material history shall be documented: this includes supplied and removed amount to the build cycle as well as batch allocation;

5) transport from AM machine – applicable for powder: unique marking of used feedstock is maintained for batch control until the next process step is determined to avoid cross-contamination.

4.4 Requirements for pre-processing: system set-up

Figure 4 shows the individual steps of the system set-up to be performed by the part manufacturer.

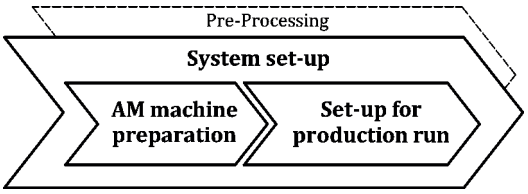

Figure 4 — Elements of the system set-up