INTERNATIONAL STANDARD

ISO/ASTM 52920

First edition
2023-06

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

Reference number
ISO/ASTM 52920:2023(E)

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Published in Switzerland

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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).

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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.

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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.

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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.

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