

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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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.

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.