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Additive manufacturing — Qualification principles — Installation, operation and performance (IQ/OQ/PQ) of PBF-LB equipment

Fabrication additive — Principes de qualification — Installation, fonctionnement et performances (IQ/OQ/PQ) de l'équipement de PBF-LB

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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.

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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 is a machine-centric process. This document provides recommended practices for machine-related process qualification for serial production of metal parts produced with the powder bed fusion by laser beam process (PBF-LB/M). This document is addressed to organizations that already have a comprehensive quality system in place.

While this document is process specific, it is intended to apply to any industry with strict quality requirements. In such industries, it is not possible to complete machine qualification without ensuring repeatable production of the desired process result, given the current state of AM process knowledge. Operational quality and part performance quality sections are included for this reason.

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Additive manufacturing — Qualification principles — Installation, operation and performance (IQ/OQ/PQ) of PBF-LB equipment

1 Scope

This document addresses installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ) issues directly related to the additive manufacturing system that has a direct influence on the consolidation of material. The first three elements of process validation, process mapping, risk assessment, and validation planning, are necessary pre-conditions to machine qualification, however, they are outside the scope of this document.

This document covers issues directly related to the AM equipment and does not cover feedstock qualification or post processing beyond powder removal.

Physical facility, personnel, process and material issues are only included to the extent necessary to support machine qualification.

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*

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 http://www.electropedia.org/

3.1
installation qualification
IQ
establishment by objective evidence that all key aspects of the process equipment and ancillary system installation adhere to the manufacturer's approved specification and that the recommendations of the supplier of the equipment are suitably considered

3.2
operational qualification
OQ
establishment by objective evidence process control limits and action levels which result in product that meets all predetermined requirements

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3.3
performance qualification
PQ
establishment by objective evidence that the process, under anticipated conditions, consistently produces a product which meets all predetermined requirements

3.4
calibration
verification of an instrument's accuracy against a standard

3.5
verification
confirmation by examination and provision of objective evidence that the specified requirements have been fulfilled

Note 1 to entry: Verification may include end product testing.

3.6
process validation
establishment by objective evidence that a process consistently produces result of product meeting its predetermined requirements

Note 1 to entry: See Note in 5.1.

3.7
system acceptance test
series of documented procedures and tests agreed between equipment supplier and equipment purchaser with results meeting predetermined requirements

Note 1 to entry: Satisfactory completion typically constitutes a procurement milestone and can be tied to payments.

3.8
build interruption
unplanned stop or delay during the build cycle

3.9
means of compliance
method used to satisfy audit requirement

3.10
factory acceptance test
FAT
system acceptance test (3.7) performed at equipment supplier's facility

3.11
site acceptance test
SAT
system acceptance test (3.7) performed after installation of machine at customer facility

4 Abbreviated terms

The following abbreviated terms are used in this document.

AM additive manufacturing

FAT factory acceptance test

FAI first article inspection

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