TECHNICAL SPECIFICATION

ISO/ASTM TS 52930

First edition

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

PROOF/ÉPREUVE

Reference number
ISO/ASTM TS 52930:2021(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11

Email: copyright@iso.org
Website: www.iso.org

ASTM International
100 Barr Harbor Drive, PO Box C700
West Conshohocken, PA 19428-2959, USA
Phone: +610 832 9634
Fax: +610 832 9635
Email: khooper@astm.org
Website: www.astm.org

Published in Switzerland

Contents

Page

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).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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.

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.

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 — Terminology*

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

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

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

IQ installation qualification

NDT non-destructive testing

OQ operational qualification

OEM original equipment manufacturer

PQ performance qualification

SAT site acceptance test

SPC statistical process control

5 General concepts

5.1 General

Assurance of product quality is derived from careful attention to many factors including selection of parts and materials, product and process design, control of the process, equipment installation and maintenance, and in-process and end-product testing. By managing these factors, a machine user can establish confidence that all manufactured units from successive manufacturing lots will be acceptable.

The basic principles of quality assurance have as their goal the production of articles that are fit for their intended use. These principles can be stated as follows:

— quality, safety, and effectiveness shall be designed and built into the end product;

— acceptable quality of the finished product is dependent upon implementing satisfactory quality controls throughout the manufacturing process and consideration at the inspection and testing stage only is not sufficient. Testing and inspection proves the quality of the product;

— each step of the manufacturing process shall be controlled to maximize the probability that the finished products meet all applicable quality and design specifications.

Process validation is a key element in assuring that these quality assurance goals are met. Note: In some industries, for example aerospace, this element is referred to as special process qualification.

Routine end-product testing alone often is not sufficient to assure product quality for several reasons:

a) some end-product tests have limited sensitivity;

b) destructive testing would be required in some cases to show that the manufacturing process was adequate;

c) in some situations end-product testing does not reveal all variations that can occur in the product that can impact on safety and effectiveness.

Successfully validating a process can reduce the dependence upon intensive in-process and finished product testing. It should be noted that in most cases, end-product testing plays a major role in assuring that quality assurance goals are met (i.e. validation and end-product testing are not mutually exclusive). Critical process variables shall be identified, monitored and documented by the machine user. Analysis of the data collected from monitoring will be used to establish the variability of process parameters for individual runs to assure that the process is under control. The machine user will then verify whether the equipment and process controls are adequate to enable product specifications to be met. These activities are part of statistical process control (see 6.3 Clause 2 and Annex A).

Finished product and in-process test data can be of value in process validation, particularly in situations where quality attributes and variabilities can be readily measured. Where finished (or in-process) testing cannot adequately measure certain attributes, process validation should be derived primarily from qualification of each system used in production and from consideration of the interaction of the various systems.

5.2 Preliminary considerations

The machine user should evaluate all factors that affect product quality when designing and undertaking a process validation study. These factors can vary considerably among different products and manufacturing technologies and could include, for example, component specifications, air and water handling systems, environmental controls, equipment functions, powder storage and handling systems, shielding gas storage and delivery systems, and process control operations. No single approach to process validation will be appropriate and complete in all cases; however, the following quality activities should be undertaken in most situations:

a) the product's end use is a determining factor in the development of product (and component) characteristics and specifications;

b) all pertinent aspects of the product that impact safety and effectiveness should be considered (including performance, reliability and stability);

c) acceptable ranges or limits should be established for each characteristic to set up allowable variations in critical process variables;

d) ranges should be expressed in readily measurable terms.

Once a specification is demonstrated as acceptable, it is important that any changes to the specification be made in accordance with documented change control procedures.

6 Elements of process validation

6.1 General

Validation shall be considered when a new product is introduced, when there is a change in the product, or when there is a change in the manufacturing process that can affect the product's characteristics. The following are considered as key elements:

a) process mapping;

b) risk assessment;

c) validation planning – identify processes that need validation;

d) installation qualification;

e) operational qualification;

f) performance qualification.

While the first three elements listed (process mapping, risk assessment, and validation planning) are key elements of process validation; they are outside the scope of this guideline. When planning for validation it is important to take in consideration different sizes of product, structure, and volume of production.

It is essential that the validation programme is documented and that the documentation is properly maintained. Approval and release of the process for use in routine manufacturing should be based upon a review of all the validation documentation, including data from the equipment qualification, process performance qualification, and product testing to ensure compatibility with the process.

For routine production, it is important to adequately record process details (e.g. time, temperature, equipment used). Documentation requirements should be part of the machine user’s quality system. Maintenance logs and build logs can be useful in performing failure investigations concerning a specific manufacturing lot. Process development data (along with specific test data) can also determine expected variance in product or equipment characteristics.

6.2 Installation qualification (IQ)

6.2.1 General

Installation qualification studies establish confidence that the process equipment and ancillary systems are capable of consistently operating within established limits and tolerances. After process equipment is designed or selected, it should be evaluated and tested to verify that it is capable of operating satisfactorily within the operating limits required by the process. This phase of validation includes examination of equipment design, determination of calibration, maintenance, and adjustment of critical equipment features that could affect the process and product. Information obtained from these studies should be used to establish written procedures covering equipment calibration, maintenance, set-up, monitoring, and control.

In assessing the suitability of a given piece of equipment, it is usually insufficient to rely solely upon the representations of the equipment supplier, or upon experience in producing some other product. Sound theoretical and practical engineering principles and considerations are a first step in the assessment.

It is important that equipment qualification simulate actual production conditions, including those that are at extreme limits of the process. These conditions shall be defined and rationalized by the user of the equipment based on the OEM's machine specifications.

Tests and challenges should be repeated as necessary to assure reliable and meaningful results. All acceptance criteria need to be met during the test or challenge. If any test or challenge shows that the equipment does not perform within its specifications, an evaluation should be performed to identify the cause of the failure. Corrections should be made, and additional test runs performed as needed, to verify that the equipment performs within specifications. The observed variability of the equipment between and within runs can be used as a basis for determining the total number of trials selected for the subsequent performance qualification studies of the process.

6.2.2 Specific considerations for installation qualification

a) Equipment design validation and installation:

   1) system acceptance testing should be completed and documented during the installation. The equipment supplier should perform a system acceptance test regardless of whether the equipment purchaser requires one:

      i) system acceptance testing can include the following:

         aa) factory acceptance testing (FAT) performed at the equipment supplier prior to delivery:

         — equipment purchaser and equipment supplier should agree in advance on FAT acceptance criteria and data to be collected. Results of the FAT should be documented and delivered to the machine user;

         — if measurements are being taken, verify calibration status for measurement devices;

         — as an example of areas that might be included, see ISO/ASTM 52941;