Technical Specification

ISO/ASTM TS 52949

First edition
2025-01

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

Fabrication additive de métaux — Principes de qualification — Installation, fonctionnement et performances (IQ/OQ/PQ) des équipements PBF-EB

Reference number
ISO/ASTM TS 52949:2025(en)

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 document 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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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, 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 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 electron beam process (PBF-EB/M). Since this process is very similar to the PBF-LB/M this document references ISO/ASTM TS 52930 pointing only the differences on the validation processes. 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 of metals — Qualification principles — Installation, operation and performance (IQ/OQ/PQ) of PBF-EB 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*

ISO/ASTM/TS 52930, *Additive manufacturing — Qualification principles — Installation, operation and performance (IQ/OQ/PQ) of PBF-LB equipment*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/ASTM 52900, ISO/ASTM TS 52930 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/

4 Abbreviated terms

For the purpose of this document the abbreviated terms in ISO/ASTM TS 52930 apply.

5 General concepts

In accordance with ISO/ASTM TS 52930, 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.

For the purpose of this document the general concepts given in ISO/ASTM TS 52930:2021, Clause 5 apply.

6 Elements of process validation

6.1 General

In accordance with ISO/ASTM TS 52930, 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 identification of key elements and their relevance for validation as defined in ISO/ASTM TS 52930:2021, 6.1 apply.

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.

The steps for this qualification are defined in ISO/ASTM TS 52930:2021, 6.2.

6.2.2 Specific considerations for installation qualification

While specific considerations for installation qualification as defined in ISO/ASTM TS 52930:2021, 6.2.2 apply, for PBF-EB/M process the following additional considerations shall be observed:

a) Equipment validation shall include a documented environment electro-magnetic field measurement, accordingly to the OEM recommendations. Instruments shall be calibrated periodically, and the calibration records maintained.

b) Verification for all utilities conforming to the information provided by the OEM.

c) Procedure control for build preparation and powder bed manufacture shall also include:

   — vacuum chamber seals check;

   — build shields assembly.

d) Preventive maintenance

   1) OEM should provide guidance to frequency, content and tools needed for preventive maintenance. Procedures should be in place to establish a preventive maintenance program. The procedure should ensure that records of maintenance are duly recorded and stored, and that risk analysis is performed for any unplanned maintenance:

      — maintenance plans can include and are not limited to the following machine sub-systems:

         aa) power supply;

         bb) beam to mechanical alignment;

         cc) beam cooling equipment;

         dd) process gas system;

         ee) filtering systems;

         ff) cooling water conductivity;

         gg) beam output using a calibrated instrument;

hh) beam profile;

ii) beam features including focus, scan field, power, current and relative position;

jj) powder spreading device;

kk) machine ways and bearings;

ll) machine interlocks and safety checks;

mm) Z-axis travel;

nn) gas lines;

oo) pumps;

pp) seals and gaskets;

qq) sieving system;

rr) purge check;

ss) heating systems;

tt) vacuum system;

uu) X-Ray leakage check.

6.3 Operational qualification (OQ)

6.3.1 General

Successful completion of equipment IQ is a pre-requisite to OQ. In accordance with ISO/ASTM TS 52930, the purpose of operational qualification is to provide rigorous testing to demonstrate the effectiveness and reproducibility of the process. Process characterization is a pre-requisite OQ to determine the process window for each of the critical process variables.

6.3.2 Specific considerations for operational qualification

As described in ISO/ASTM TS 52930:2021, 6.3.2 the purpose of OQ is to show the relationship of the input variables to the measured output for the specific combination of equipment with specific part or family of parts to be produced. Critical and optimized process parameters that lead to acceptable quality levels and process capability (for manufacturing processes) or acceptable accuracy, precision, and sensitivity should be recorded as 'Baseline Settings' and should establish the build parameters for subsequent builds once the qualification builds have been validated. Such settings can include but are not limited to:

a) beam – checked across entire build platform (or specified area, if agreed with AM machine user):

   1) beam diameter, power, current and mode;

   2) location of focus point versus build surface;

   3) beam alignment;

   4) scan strategy;

b) powder:

   1) chemistry;

   2) morphology;

3) size distribution;

c) layer thickness and uniformity:

1) powder spreading device material and wear. The effect of foreign particles detached from a worn out recoater should be assessed.

NOTE Powder spreading device blades are normally stainless steel, feedstock material can be Ti, Cu, CrCo or tool steel.

2) recoater speed;

3) number of swipes per layer;

4) powder refill rate;

d) incremental build platform movement;

e) part orientation;

f) build volume;

g) powder bed temperature;

h) powder deposition settings;

i) chamber atmosphere:

1) vacuum control gas;

2) pressure;

3) temperature.

In entering the performance qualification phase of validation, it is understood that the process specifications have been established and essentially proven acceptable through laboratory or other trial methods and that the equipment has been judged acceptable on the basis of suitable installation studies.

6.4 Performance qualification (PQ)

6.4.1 General

Performance qualification elements and their relevance are described in ISO/ASTM TS 52930:2021, 6.4 otherwise described as follow.

Successful completion of OQ is a pre-requisite to starting PQ. In accordance with ISO/ASTM TS 52930, critical process input and output variables should be monitored and documented. Analysis of the data collected from monitoring will establish the relative impacts of input ranges and subsequent variability on the critical process output variables to confirm that a process is in control. This analysis will establish whether the equipment and process controls are adequate to ensure that the product specification is met.

6.4.2 Specific considerations for performance qualification

6.4.2.1 Critical process input and output variables

For product performance qualification, the variables which have been determined in OQ to have an effect on the quality of the output shall be monitored and controlled using appropriate procedures and frequency determined and documented by the AM machine user. For PBF-EB processes, the following variables are deemed to have such effect:

a) beam current, spot size, layer exposure time;

b) scan strategy and speed;

c) layer thickness;

d) hatching strategy;

e) vacuum control, pressure and level;

f) build platform material, condition and preparation;

h) process preheat temperature;

i) build space temperature;

j) recoater blade wear;

k) ambient environmental conditions (e.g. temperature, humidity, strong electromagnetic fields);

l) feedstock condition:

   1) powder lot change;

   2) content of recycled powder such as chemical constituency, particle size distribution, and morphology.

The possible effects in output due to excursions of these parameters are defined in ISO/ASTM TS 52930:2021, 6.4.1.1,

6.4.2.2 In-process monitoring

Where in-process monitoring is available then it can be utilized. Examples of in-process monitoring are provided in Table 1:

Table 1 — Examples of in-process monitoring

Measured data	Means of monitoring	Potential impact on output
Melt pool temperature and chemistry	Infrared spectroscopy (IR) Optical emission spectroscopy (OES)	'Lack of fusion' defects Largely used for highlighting dosing issues during the build or for trouble-shooting post-build
2D images of build layer	Camera/Electron optical image	
Electrons back scatter / Particles in suspension ("smoke") detection	X-Ray camera/Electron optical image	Excess of smoke can deviate the beam and cause arc trips that stops the build prematurely.
Inclusion Detection (feedstock contamination) image contrast	X-Ray camera	Changing part properties within build job
Defect Detection /Porosity detection/ measurement	X-Ray camera	Insufficient part properties

7 Revalidation

A quality assurance system should be in place, and this requires that any changes to previously qualified materials, equipment or processes be revalidated whenever these changes can impact on product effectiveness or product characteristics. Furthermore, the machine user should consider subtle, potentially adverse, differences in the raw material characteristics following a change in raw material supplier. Any identification of adverse differences indicates a need to revalidate the process.

One way of detecting the kind of changes that should initiate revalidation is the use of tests and methods of analysis which are capable of measuring characteristics that can vary. Such tests and methods usually yield specific results which go beyond the mere pass/fail basis, thereby detecting variations within product and