



SLOVENSKI STANDARD
kSIST FprCEN ISO/ASTM/TS 52930:2021
01-maj-2021

[Not translated]

Additive Manufacturing - Qualification principles - Installation, operation and performance (IQ/OQ/PQ) of PBF-LB equipment (ISO/ASTM PRF TS 52930:2021)

Additive Fertigung - Grundlagen der Qualifizierung - Installation, Funktion und Leistung (IQ/OQ/PQ) von PBF-LB-Anlagen (ISO/ASTM PRF TS 52930:2021)

iTeh STANDARD PREVIEW

Fabrication additive - Principes de qualification - Installation, fonctionnement et performances (IQ/OQ/PQ) de l'équipement de PBF-LB (ISO/ASTM PRF TS 52930:2021)

[kSIST FprCEN ISO/ASTM/TS 52930:2021](https://standards.iteh.ai/catalog/standards/sist/6f751898-2b5b-4729-a1da-4a144cfe4cc7/ksist-fprcen-iso-astm-ts-52930-2021)

[https://standards.iteh.ai/catalog/standards/sist/6f751898-2b5b-4729-a1da-](https://standards.iteh.ai/catalog/standards/sist/6f751898-2b5b-4729-a1da-4a144cfe4cc7/ksist-fprcen-iso-astm-ts-52930-2021)

[4a144cfe4cc7/ksist-fprcen-iso-astm-ts-52930-2021](https://standards.iteh.ai/catalog/standards/sist/6f751898-2b5b-4729-a1da-4a144cfe4cc7/ksist-fprcen-iso-astm-ts-52930-2021)

Ta slovenski standard je istoveten z: FprCEN ISO/ASTM/TS 52930

ICS:

25.030

3D-tiskanje

Additive manufacturing

kSIST FprCEN ISO/ASTM/TS 52930:2021 en,fr,de

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[kSIST FprCEN ISO/ASTM/TS 52930:2021](https://standards.iteh.ai/catalog/standards/sist/6f751898-2b5b-4729-a1da-4a144cf4cc7/ksist-fprcen-iso-astm-ts-52930-2021)

<https://standards.iteh.ai/catalog/standards/sist/6f751898-2b5b-4729-a1da-4a144cf4cc7/ksist-fprcen-iso-astm-ts-52930-2021>

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*
(standards.iteh.ai)

[ksIST FprCEN ISO/ASTM/TS 52930:2021](https://standards.iteh.ai/catalog/standards/sist/6f751898-2b5b-4729-a1da-4a144cf4cc7/ksist-fprcen-iso-astm-ts-52930-2021)
<https://standards.iteh.ai/catalog/standards/sist/6f751898-2b5b-4729-a1da-4a144cf4cc7/ksist-fprcen-iso-astm-ts-52930-2021>

PROOF / ÉPREUVE



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

© ISO/ASTM International 2021

iTeh STANDARD PREVIEW (standards.iteh.ai)

[kSIST FprCEN ISO/ASTM/TS 52930:2021](https://standards.iteh.ai/catalog/standards/sist/6f751898-2b5b-4729-a1da-4a144cfe4cc7/ksist-fprcen-iso-astm-ts-52930-2021)
<https://standards.iteh.ai/catalog/standards/sist/6f751898-2b5b-4729-a1da-4a144cfe4cc7/ksist-fprcen-iso-astm-ts-52930-2021>



COPYRIGHT PROTECTED DOCUMENT

© ISO/ASTM International 2021

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester. In the United States, such requests should be sent to ASTM International.

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

Published in Switzerland

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

Contents		Page
Foreword		iv
Introduction		v
1 Scope		1
2 Normative references		1
3 Terms and definitions		1
4 Abbreviated terms		2
5 General concepts		3
5.1 General.....		3
5.2 Preliminary considerations.....		4
6 Elements of process validation		4
6.1 General.....		4
6.2 Installation qualification (IQ).....		5
6.2.1 General.....		5
6.2.2 Specific considerations for installation qualification.....		5
6.3 Operational qualification (OQ).....		8
6.3.1 General.....		8
6.3.2 Specific considerations for operational qualification.....		9
6.4 Performance qualification (PQ).....		11
6.4.1 General.....		11
6.4.2 Specific considerations for performance Qualification.....		11
6.4.3 Deterioration of products.....		13
7 Revalidation		13
Annex A (normative) Process capability evaluation (Statistical process control)		15
Bibliography		19

ISO/ASTM TS 52930:2021(E)

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.

iTeh STANDARD PREVIEW (standards.iteh.ai)

[kSIST FprCEN ISO/ASTM/TS 52930:2021
https://standards.iteh.ai/catalog/standards/sist/6f751898-2b5b-4729-a1da-4a144cf4cc7/ksist-fprcen-iso-astm-ts-52930-2021](https://standards.iteh.ai/catalog/standards/sist/6f751898-2b5b-4729-a1da-4a144cf4cc7/ksist-fprcen-iso-astm-ts-52930-2021)

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[kSIST FprCEN ISO/ASTM/TS 52930:2021](https://standards.iteh.ai/catalog/standards/sist/6f751898-2b5b-4729-a1da-4a144cf4cc7/ksist-fprcen-iso-astm-ts-52930-2021)

<https://standards.iteh.ai/catalog/standards/sist/6f751898-2b5b-4729-a1da-4a144cf4cc7/ksist-fprcen-iso-astm-ts-52930-2021>

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

ISO/ASTM TS 52930:2021(E)**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

[kSIST FprCEN ISO/ASTM/TS 52930:2021](https://standards.iteh.ai/catalog/standards/sist/6f751898-2b5b-4729-a1da-4b11c1e1e1e1/kSIST-FprCEN-ISO-ASTM-TS-52930-2021)

<https://standards.iteh.ai/catalog/standards/sist/6f751898-2b5b-4729-a1da-4b11c1e1e1e1/kSIST-FprCEN-ISO-ASTM-TS-52930-2021>

[standards.iteh.ai](https://standards.iteh.ai/catalog/standards/sist/6f751898-2b5b-4729-a1da-4b11c1e1e1e1/kSIST-FprCEN-ISO-ASTM-TS-52930-2021)

**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.