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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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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, 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 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 — 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

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

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 6.3.2 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 product's 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;

bb) site acceptance testing (SAT) performed following the installation activity at the equipment user site by the equipment supplier (equipment user involved or witnessing);

ii) examine equipment design and locate supplied documentation, prints, drawings, and manuals, including where applicable, software documentation:

aa) establish a filing location to safely retain the supplied equipment documents;

iii) the user should generate or locate a spare parts list with guidance from the OEM;

2) installation conditions:

i) there should be a documented procedure for humidity, temperature and other environmental conditions (vibration, etc.) for the machine location:

aa) environmental conditions and limits shall be specified by the OEM. Verification that the facility is in compliance and able to adequately control and monitor environmental conditions is the responsibility of the user:

— procedures and equipment used to monitor the environmental conditions should be recorded in the IQ report.

— humidity and temperature shall each be measured in at least one representative location in the vicinity of the equipment. Instruments shall be calibrated periodically and the calibration records maintained.

— consider allowable limits on other environmental factors such as vibration;

NOTE For systems where powder shall be exposed to atmosphere during loading or other handling operations, direct effects on the powder shall also be considered in setting appropriate limits.

bb) The surrounding work area should fulfil the requirements specified by the OEM and have sufficient space to perform the processing and associated activities. Location of equipment should allow for adequate servicing, ventilation, and safety;

cc) OEMs are responsible for providing facilities guides detailing siting requirements prior to system installation. User is responsible for meeting facility requirements prior to install of the equipment;

ii) verify that all utilities are conforming:

aa) determine machine requirements based on information that shall be provided by OEM. The OEM should be consulted for specific system facility requirements prior to installation. Utilities can include:

— electricity;

— inert gas;

— compressed air;

— chill water;

— exhaust;

— electrostatic bonding or grounding;

— computer network or other communications connections, if applicable;

b) procedure control:

1) OEM shall provide adequate instruction and documentation on how to properly operate equipment;

2) as part of the installation qualification the user should establish proper documented control of the AM equipment and supporting equipment. Such written instruction can include the following and should be documented within the IQ:

   i) Build preparation and powder bed manufacture- including:

      — machine start-up;

      — establishment of process conditions;

      — build set-up;

      — cleaning of build platform;

      — build platform removal;

      — build monitoring;

      — post build (e.g. removal of loose powder and build platform);

      — build platform traceability;

   ii) powder storage, handling, traceability (labelling conventions) and waste disposal;

   iii) configuration management;

   iv) nonconforming material in case of build interruption or build anomaly;

   v) file preparation;

   vi) control of digital workflow;

c) software and data control:

   1) data management should be a documented process according to ISO/ASTM 52920[1)];

   2) software used for file preparation and operation of the AM equipment should be characterized and (configuration) controlled;

   3) the user should have a documented procedure for configuration management to ensure that software versions are controlled and recorded on manufacturing build records;

   4) software updates should be controlled following a written procedure;

   5) based on industry and application further software validation can be required;

d) calibration of machines and subsystems:

   1) equipment calibration:

      i) establish calibration, adjustment, performance tests and expected repair procedures (including schedules):

         aa) calibration schedules of instruments and measurement devices used either within the process or as part of the calibration of the system shall be determined. Procedures should be in place to ensure compliance to calibration system. Refer to ISO/IEC 17025 or internal calibration standard;

         bb) specific recalibration intervals depend on a number of factors including:

         — accuracy requirements set by customers;

         — requirements set by contract or regulation;

1) Under preparation. Stage at the time of publication ISO/ASTM/CD 52920:2021.

— inherent stability of the specific instrument or device;

— environmental factors that can affect the stability;

e) preventive maintenance

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

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

aa) power supply;

bb) optical to mechanical alignment;

cc) laser cooling equipment;

dd) process gas system;

ee) filtering systems;

ff) cooling water conductivity;

gg) laser output using a calibrated instrument;

hh) laser beam profile;

ii) optical components including focus, scan field, power and relative position;

jj) recoater arm and wiper blades;

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;

f) performance testing

performance testing consists of machine trials that test the capability of the equipment to execute processes that will be used during production operation. Depending on the situation, some performance testing can be included in system acceptance testing. Performance testing can also be part of OQ.

6.3 Operational qualification (OQ)

6.3.1 General

The purpose of operational qualification is to provide rigorous testing to demonstrate the effectiveness and reproducibility of the process. Process characterization to determine the process window for each

of the critical process variables is a pre-requisite. The extent to which process characterization should be performed is a function of production quantities.

Each process should be defined and described with sufficient specificity so that employees understand what is required. Parts of the process which can vary so as to affect important product quality should be challenged. In challenging a process to assess its adequacy, it is important that challenge conditions simulate those that will be encountered during actual production, including conditions at the extreme limits of the process. The challenges should be repeated enough times to assure that the results are meaningful and consistent. Annex A includes details on process capability evaluation.

Each individual manufacturing process should be appropriately qualified and validated. There is an inherent danger in relying on what are perceived to be similarities between products, processes, and equipment without appropriate challenge.

It is important that the machine user prepares a written validation protocol which specifies the procedures (and tests) to be conducted and the data to be collected. The purpose for which data are collected shall be clear, the data shall reflect facts and be collected carefully and accurately. The protocol should specify a sufficient number of replicate process runs to demonstrate reproducibility and provide an accurate measure of variability among successive runs. The replicate number should be defined by machine user based on hypothesised risk and/or preferably historical data. The test conditions for these runs should encompass upper and lower processing limits and circumstances, including those within standard operating procedures, which pose the greatest chance of process or product failure compared to ideal conditions (they are sometimes called "most appropriate challenge" conditions). Validation documentation should include evidence of the suitability of materials and the performance and reliability of equipment and systems.

6.3.2 Specific considerations for operational qualification

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. A written procedure should be in place by the user to establish documented control and operational procedures to ensure the powder bed machine and removable components are capable of consistently producing acceptable parts. For larger volume production, ongoing sampling is required (at frequency and quantity agreed on a case-by-case basis) to ensure consistency of manufacture.

a) For manufacturing processes, OQ is performed by challenging the process control limits determined during OQ, in order to prove that the limits are valid and show the process capability and stability. Challenges to the process should simulate conditions that might be encountered during actual manufacturing.

b) During OQ, process parameters shall be challenged in order to:

   1) identify critical input variables that affect process outputs;

   2) assure that input variables will result in a product (or measurement in the case of a test method) that meets all defined requirements under all anticipated conditions of operation, including extreme limits of the process;

   3) identify and eliminate any controllable sources of process variation;

   4) determine optimal processing parameters and acceptance criteria;

   5) identify various process control limits / action levels that will enable adjustment of the process during routine production to maintain a state of control (i.e., avoid approaching worst-case conditions).

c) Critical process parameters:

   1) for manufacturing processes, statistical techniques such as design of experiments, control charts and capability studies can be used to optimize the process, its capability and stability;

2) 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 establish the build parameters for subsequent builds, once the qualification builds have been validated. Such settings can include but are not limited to:

   i) laser – checked across entire build platform (or area, if agreed with equipment user):

      I) beam diameter, power and mode;

      II) location of focus point versus build surface;

      III) multi laser alignment;

      IV) scan strategy;

   ii) powder:

      I) chemistry;

      II) morphology;

      III) size distribution;

   iii) layer thickness and uniformity:

      I) recoater blade material and wear. The effect of foreign particles detached from a worn out recoater should be assessed;

      II) recoater speed;

      III) number of swipes per layer;

      IV) powder refill rate;

   iv) incremental build platform movement;

   v) part orientation;

   vi) build volume;

   vii) build platform temperature;

   viii) powder deposition settings;

   ix) chamber atmosphere:

      I) gas composition;

      II) impurity concentration;

      III) pressure;

      IV) temperature;

      V) gas flow – velocity profile.

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

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.

Potential production variables can include shift, day, operators, or any quantity that affects performance over time.

Before concluding that a process has been successfully validated, it is necessary to demonstrate that the qualification process has not adversely affected the finished product. Where possible, product PQ testing should include performance testing under conditions that simulate actual use. The scope of product PQ testing is subject to agreement between the machine user and the customer but should be conducted using a product manufactured from the same type of production equipment, methods and procedures used for routine production. Otherwise, the qualified product could be non-representative of production units and cannot be used as evidence that the manufacturing process will produce a product that meets the pre-determined specifications and quality attributes.

Following product PQ for production units, a formal technical review should be conducted that includes:

a) validation that the physical product satisfies the requirements within the approved product specification;

b) determination of the validity of test methods and equipment used to determine compliance with the approved specifications;

c) confirmation of the adequacy of the specification change control programme.

6.4.2 Specific considerations for performance qualification

6.4.2.1 Critical process input and output variables

Control of the following variables are deemed to have an effect on the quality of the output. 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-LB processes, the following variables are deemed to have such effect:

a) laser power, spot size, layer exposure time;

b) scan strategy and speed;

c) layer thickness;

d) hatching strategy;

e) inert gas type, purity, pressure and flowrate;

f) process gas parameters for example purity, pressure and flowrate;

g) build platform material, condition and preparation;

h) substrate preheat temperature;

i) build space temperature and pressure;

j) recoater blade or roller wear;

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

l) feedstock condition:

   1) powder lot change;

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

Possible effects in output due to excursions of these parameters are:

— failed build or unplanned stoppage;

— increased porosity;

— lack of fusion;

— excessive residual stresses, leading to warpage, cracking or delamination;

— inconsistency of part dimension;

— inconsistency of material properties:

   1) microstructure;

   2) mechanical;

   3) chemistry;

— contamination within formed material;

— unsatisfactory surface finish.

6.4.2.2 Production controls

Procedures and/or work instructions should include the following:

a) sequence of operations defined in route/job card with:

   1) sign-off for each operation by qualified operator;

   2) manufacturing information, such as machine identification number, powder batch identification, unique build identification;

   3) critical process input variables specified (or reference to specific build parameter file that defines those variables);

b) pre-build checks (e.g. build platform material, size, parallelism, thickness, surface roughness);

c) post-build checks (e.g. removal of unfused powder, build platform removal, visual inspection of build).

6.4.2.3 In-process monitoring

The three-dimensional changes in geometry, varying heat transfer mechanisms and local variances in the feedstock contribute to variable cooling rates and hence, the resultant variations in thermal profile of the fused material. In-process measurement data and resulting finished product test data can be of value when validating the process, particularly in situations where quality attributes and variabilities can be readily measured.

Where in-process monitoring is available then it should be utilized. Examples of in-process monitoring are provided below:

Table 1 — Examples of in-process monitoring

Measured data	Means of monitoring	Potential impact on output
Laser energy intensity	Photodiode	Depth-width ratio of melt pool
Melt pool temperature and chemistry	Infrared spectroscopy (IR)	'Lack of fusion' defects
	Optical emission spectroscopy (OES)	Largely used for highlighting dosing issues during the build or for trouble-shooting post-build
2D images of build layer	Camera	

6.4.2.4 Single part/batch manufacture

In some cases, a part can be manufactured individually or on a one-time basis; product performance qualification can have limited applicability in these cases. However, data obtained during the manufacturing process can be used in conjunction with product and specimen testing to demonstrate that the single build yielded a finished product that met all specification requirements and quality characteristics. Because no statistical process control is possible for single part production, evaluation of this collected data is expected to be extensive.

6.4.3 Deterioration of products

Continuous monitoring and data collection from the process will enable the identification of events or trends that lead towards the deterioration of product quality. A documented procedure should be established that instructs the operator on actions to take when such an event is encountered (e.g. build interruption) or trend identified (e.g. increasing distortion).

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 could 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 process specifications and allowing determination of whether a process is slipping out of control. This is a fundamental purpose of statistical process control.

The quality assurance procedures should establish the circumstances under which revalidation is required. These can be based upon equipment, process, and product performance observed during the initial validation challenge studies. It is desirable to designate individuals who have the responsibility to review product, process, equipment and personnel changes to determine if and when revalidation is warranted. Examples of circumstances under which requalification might be required are:

a) software/firmware update of the AM equipment;

b) installation of additional components;

c) repair or replacement of components;

d) changes to equipment location or operating environment;

e) rejection of an additively manufactured part;

f) expiration of qualification validity period.

The extent of revalidation will depend upon the nature of the changes and how they impact different aspects of production that had previously been validated. It could be unnecessary to revalidate a process

entirely, merely because a given circumstance has changed. However, it is important to carefully assess the nature of the change to determine potential ripple effects and what needs to be considered as part of revalidation.

Annex A
(normative)

Process capability evaluation (Statistical process control)

A.1 General

This annex provides guidance for process capability evaluation by calculation of process capability indexes (CpK values). These indexes are calculated to validate and document reproducible part specific KPIs and perform statistical process control.

The execution of this process capability evaluation becomes particularly applicable to the production of statically relevant part quantities.

A.2 Initial state

The first step towards process capability evaluation is to establish the initial state by specifying and locking the following three boundary conditions (see Figure A.1):

a) material conditions;

b) test artefacts;

c) process conditions.

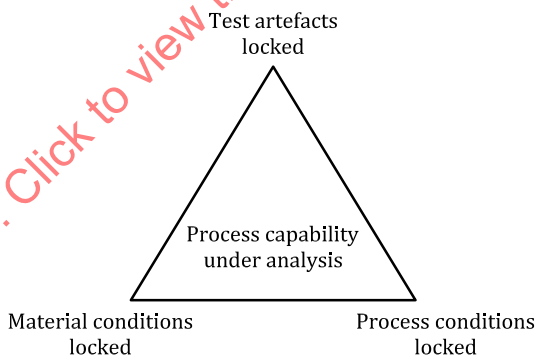

Figure A.1 — Locked conditions during process capability evaluation

A.2.1 Regarding material conditions: The initial state of the powder should be as specified by the material supplier (e.g. according to ISO/ASTM 52907). The powder should be handled according to the specifications of the material supplier (see also ISO/ASTM 52920:—, 4.3). Pre conditioning should be done according to the material supplier specifications and/or the OEM's specifications.

A.2.2 Regarding test artefacts: These should be chosen on standardized level dependent on the tested properties (end-part dependent KPI).

A.2.3 Regarding the process conditions: These comprise the environmental conditions and the AM machine conditions. Environmental conditions, such as temperature, humidity, services/utilities and shocks/vibrations, should be as constant as possible and meet the required ranges specified by the OEM's instructions (see also ISO/ASTM 52941). The AM machine and peripheric devices should be installed, operated and maintained according to their specifications and Clause 6.

A.3 Process capability evaluation

When the initial state (see A.2) has been set, a process capability evaluation should be performed, considering:

A.3.1 Selecting feedstock: The materials shall be chosen, which are in the field of application (declared by the OEM) to produce end-parts.

A.3.2 Selecting KPIs to be examined to verify product requirements: The KPIs should be chosen to meet relevant requirements from the end-parts target industries. Within literature popular KPI's are:

a) dimensional and geometric accuracy (possible: sloping planes, curved surfaces, thin planes, planes positioned at different angles, overhangs, small holes, cooling chambers and cylinders, sharp corners and edges, and fine details/features, minimum wall thickness);

b) surface roughness;

c) alloy composition;

d) hardness;

e) tensile strength;

f) density.

A.3.3 Selecting test artefacts depending on selected KPIs: In general, positioning, coordinates and orientations should be defined according to ISO/ASTM 52921 for each test subject. The following information assists on choosing the test artefacts related to the KPIs. In principle, standardized test artefacts such as geometrical accuracy based on ISO/ASTM 52902 should be preferred. For more part specific test artefacts, individual test artefacts may be preferred or added. To get statistically relevant results for the CpK calculation, at least 50 test artefacts per KPI should be produced. The amount of test artefacts per KPI should be divided into at least five production runs.

A.3.4 Selecting process parameters: The process parameters to produce test artefacts should be chosen to achieve the best possible results in general. To gain traceability and the relation between quality and productivity, the resulting build rate (cm^3/h) should be given for each parameter set.

A.3.5 Selecting testing and measurement methods: Testing and measuring of test artefacts should be performed in accordance with ISO 17296-3 or specific test artefact standards such as ISO/ASTM 52902 for geometrical accuracy.

A.3.6 Calculation of the process capability indexes (*CpK*): Based on the initial set lower and upper limits for the KPIs and the results of the tested artefacts, the process capability indexes should be calculated as follows:

The measured scatter of the process is expressed as six times the standard deviation of a sample of the process:

$$P_{\mathrm{p}} = \left(L_{\mathrm{up}} - L_{\mathrm{lo}}\right) / 6s$$

where

P_{p} is the process performance index;

L_{up} is the upper specification limit;