



Designation: F3434 – 20

Guide for Additive manufacturing – Installation/Operation and Performance Qualification (IQ/OQ/PQ) of Laser-Beam Powder Bed Fusion Equipment for Production Manufacturing¹

This standard is issued under the fixed designation F3434; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ϵ) indicates an editorial change since the last revision or reapproval.

INTRODUCTION

This document provides recommended practices for process qualification of metal production parts produced with the powder bed fusion by laser beam process (PBF-LB/M). This document covers only process qualification issues directly related to the AM equipment and does not cover feedstock qualification or post processing beyond powder removal.

1. Scope

1.1 This guide addresses IQ, OQ, and PQ issues directly related to the AM machine and connected equipment. Physical facility, personnel, process and material issues are only included to the extent necessary to support machine qualification.

1.2 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 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.

2.2 Normative References:

ISO/ASTM 52900 Additive Manufacturing — General Principles — Terminology

ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories

¹ This guide is under the jurisdiction of ASTM Committee F42 on Additive Manufacturing Technologies and is the direct responsibility of Subcommittee F42.05 on Materials and Processes.

Current edition approved April 15, 2020. Published July 2020. DOI: 10.1520/F3434-20.

3. Terminology

3.1 *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/>

3.2 Definitions:

3.2.1 *build interruption*—unplanned delay during the additive manufacturing cycle.

3.2.2 *build pause*—longer than typical time spacing between layers. It may be planned as part of the print job or part of automatic machine control function – for example to allow powder transfer.

3.2.3 *calibration*—verification of an instrument's accuracy against a standard.

3.2.4 *factory acceptance test*—System Acceptance Test performed at equipment manufacturer's facility.

3.2.5 *installation qualification*—establishing 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.

3.2.6 *means of compliance*—method used to satisfy audit requirement.

3.2.7 *operational qualification*—establishing by objective evidence process control limits and action levels which result in product that meets all predetermined requirements.

3.2.8 *performance/part qualification*—establishing by objective evidence that the process, under anticipated conditions, consistently produces a product which meets all predetermined requirements.

3.2.9 *process validation*—Establishing by objective evidence that a process consistently produces result of product meeting its predetermined requirements.xcazze

3.2.10 *process validation protocol*—A document stating how validation will be conducted, including test parameters, product characteristics, manufacturing equipment, and decision points on what constitutes acceptable test results.

3.2.11 *site acceptance test*—System Acceptance Test performed after installation of machine at customer facility.

3.2.12 *system acceptance test*—series of documented procedures and tests agreed between equipment supplier and equipment purchaser with results meeting predetermined requirements. Satisfactory completion typically constitutes a procurement milestone and may be tied to payments.

3.2.13 *verification*—confirmation by examination and provision of objective evidence that the specified requirements have been fulfilled. Verification may include end product testing.

4. Abbreviated Terms

The following abbreviated terms are used in this document:

AM	Additive Manufacturing
FAT	Factory Acceptance Test
FAI	First Article Inspection
KPC	Key Product Characteristic
NDT	Non-Destructive Testing
OEM	Original Equipment Manufacturer
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 manufacturer can establish a high degree of confidence that all manufactured units from successive lots will be acceptable.

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

- (1) quality, safety, and effectiveness must be designed and built into the product,
- (2) quality cannot be inspected or tested into the finished product, and
- (3) each step of the manufacturing process must be controlled to maximize the probability that the finished product meets all quality and design specifications.

5.1.2 Process validation is a key element in ensuring that these quality assurance goals are met.

5.1.3 Routine end-product testing alone often is not sufficient to ensure product quality for several reasons. Some end-product tests have limited sensitivity. In some cases, destructive testing would be required to show that the manufacturing process was adequate, and in other situations end-

product testing does not reveal all variations that may occur in the product that may impact on safety and effectiveness. However, successfully validating a process may 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 ensuring that quality assurance goals are met; that is, validation and end-product testing are not mutually exclusive.

5.1.4 Key process variables should be monitored and documented. Analysis of the data collected from monitoring will establish the variability of process parameters for individual runs to ensure that a process is in control and will establish whether the equipment and process controls are adequate to ensure that product specifications are met. These activities are part of statistical process control.

5.1.5 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*—A manufacturer should evaluate all factors that affect product quality when designing and undertaking a process validation study. These factors may vary considerably among different products and manufacturing technologies and could include, for example, component specifications, air and water handling systems, environmental controls, equipment functions, 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.

5.2.1 The product's end use should be a determining factor in the development of product (and component) characteristics and specifications. All pertinent aspects of the product that impact on safety and effectiveness should be considered. These aspects include performance, reliability and stability. Acceptable ranges or limits should be established for each characteristic to set up allowable variations. These ranges should be expressed in readily measurable terms.

5.2.2 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

Validation must be considered when a new product is introduced, there is a change in the product, or when there is a change in the manufacturing process that may affect the product's characteristics, such as uniformity and identity. The following are considered as key elements.

- (1) Process mapping,
- (2) Risk assessment,
- (3) Validation planning – identify processes that need validation,
- (4) Installation qualification,
- (5) Operational qualification, and
- (6) Performance/part qualification.

While the first three elements listed; process mapping, risk assessment, and validation planning are key elements of process validation, and are necessary pre-conditions to machine qualification, they are outside the scope of this guide. 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 program 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/package testing to ensure compatibility with the process.

For routine production, it is important to adequately record process details (for example, time, temperature, equipment used) and to record any changes to the process. Documentation requirements should be part of the machine user's quality system. A maintenance log can be useful in performing failure investigations concerning a specific manufacturing lot. Process development data (along with specific test data) may also determine expected variance in product or equipment characteristics.

6.1 *Installation Qualification (IQ)*

6.1.1 *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 requirements; and identifying 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, monitoring, and control.

6.1.1.1 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.

6.1.1.2 It is important that equipment qualification simulate actual production conditions, including those which are "worst case" situations. These conditions must be defined and rationalized by the user of the equipment based on the equipment manufacturer's machine specifications.

6.1.1.3 Tests and challenges should be repeated a sufficient number of times to ensure reliable and meaningful results. All acceptance criteria must 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.

6.1.2 *Specific Considerations for Installation Qualification*

6.1.2.1 *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.

(a) System acceptance testing may include the following:

(i) Factory Acceptance Testing (FAT) performed at the equipment supplier prior to delivery. The equipment user should witness or directly take part in the FAT.

– Equipment purchaser and equipment supplier should agree in advance on FAT acceptance criteria and data to be collected.

– If measurements are being taken, verify calibration status for measurement devices.

– As an example of areas that might be included.

(ii) Site Acceptance Testing (SAT) performed following the installation activity at the equipment user site by the equipment supplier (equipment user involved or witnessing).

(b) Examine equipment design and locate supplied documentation, prints, drawings, and manuals, including where applicable, software documentation; establish a filing location to safely retain the supplied equipment documents;

(c) The user should generate or locate a spare parts list with guidance from the OEM.

(2) Installation Conditions:

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

(i) Environmental conditions and limits shall be provided by the equipment manufacturer. 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. Note that for systems where powder must be exposed to atmosphere during loading or other handling operations, direct effects on the powder must also be considered in setting appropriate limits.

– Consider allowable limits on other environmental factors such as vibration.

(ii) The surrounding work area should have sufficient space to perform the processing and associated activities. Location of equipment must allow for adequate servicing, ventilation, and safety.

(iii) OEMs are responsible for providing facilities guides detailing siting requirements prior to system installation. The user is responsible for meeting facility requirements prior to install of the equipment.