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.

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Standard Practice for Validating the Additive Manufacturing (AM) Production Process for Medical Devices Produced Using Laser Powder Bed Fusion[1]

This standard is issued under the fixed designation F3604; 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 practice provides recommendations to perform process validation in which medical devices are manufactured using powder bed fusion by laser beam (PBF-LB/M). Areas of interest for process validation are machine qualifications, software used in the manufacturing process, the importance of design specification and verification on process validation, and raw materials.

1. Scope

1.1 This practice provides an overview of how to perform process validation for medical devices manufactured using PBF/LB/M. The topics that will be covered include machine qualifications, software used in the manufacturing process, the importance of design specification and verification on process validation, and raw materials.

1.2 This practice also provides recommendations for process characterization, risk management, additive manufacturing (AM) facility qualification, and process control as a prerequisite for qualification activity, including installation qualification/operational qualification/performance qualification (IQ/OQ/PQ).

1.3 The practice is primarily focused on non-device-specific AM system(s) validation. Additional information may be needed in reference to the performance of the actual device.

1.4 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.5 *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 *ASTM Standards:*[2]

F2971 Practice for Reporting Data for Test Specimens Prepared by Additive Manufacturing

F3049 Guide for Characterizing Properties of Metal Powders Used for Additive Manufacturing Processes

F3456 Guide for Powder Reuse Schema in Powder Bed Fusion Processes for Medical Applications for Additive Manufacturing Feedstock Materials

2.2 *ISO Standards:*[3]

ISO 9712 Non-destructive Testing—Qualification and Certification of NDT Personnel

ISO 13485 Medical Devices—Quality Management Systems—Requirements for Regulatory Purposes

ISO 14971 Medical Devices—Application of Risk Management to Medical Devices

2.3 *ISO/ASTM Standards:*[2]

52900 Additive Manufacturing—General Principles—Terminology

52902 Additive manufacturing—Test artifacts—Geometric capability assessment of additive manufacturing systems

52907 Additive manufacturing—Feedstock materials—Methods to characterize metallic powders

52910 Standard Guidelines for Design for AM

52911-1 Additive manufacturing—Design—Part 1: Laser-based powder bed fusion of metals

[1] This practice is under the jurisdiction of ASTM Committee F42 on Additive Manufacturing Technologies and is the direct responsibility of Subcommittee F42.07 on Applications.

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[2] For referenced ASTM or ISO/ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from International Organization for Standardization (ISO), ISO Central Secretariat, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland, https://www.iso.org.

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52911-2 Additive manufacturing—Design—Part 2: Laser-based powder bed fusion of polymers
52913-1 Additive manufacturing—Feedstock materials—Part 1 Parameters for characterization of powder flow properties
52915 Specification for additive manufacturing file format (AMF) Version 1.2
52920 Standard specification for quality assurance processes at AM centers
52930 Additive manufacturing—Qualification principles—Installation, operation, and performance (IQ/OQ/PQ) of PBF-LB equipment
52931 Standard guideline for use of metallic materials
52933 Standard specification on indoor air quality management
52950 Additive manufacturing—General principles—Overview of data processing

2.4 *ISO/DIS Standard:*

ISO/DIS 14644-9 Cleanrooms and associated controlled environments—Part 9: classification of surface particles cleanliness[3]

2.5 *Federal Standards:*[4]

21 CFR Part 11 Electronic Records, Electronic Signatures
21 CFR Part 820 Quality System Regulation

3. Terminology

3.1 *Definitions*—Standard additive manufacturing (AM) terminology is defined in ISO/ASTM 52900. For the purposes of this guide, the definitions in 3.2 apply. The International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) maintain terminological databases for use in standardization at the following addresses: ISO online browsing platform available at https://www.iso.org/obp and IEC Electropedia available at http://www.electropedia.org/.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *build interruption, n*—unplanned delay during the AM cycle that halts the general progression of the process.

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

3.2.3 *calibration, n*—configuration and verification of all critical sensors, accessories, and instruments against control standards defined by original equipment manufacturer (OEM) guidance.

3.2.4 *critical to quality, CTQ, n*—attribute or feature that is critical to the overall quality of the device or process.

3.2.5 *factory acceptance test, n*—system acceptance test performed at OEM facility.

3.2.6 *installation qualification, n*—establishing by objective evidence that all key aspects of the installation process associated with both the printing equipment and ancillary equipment adhere to the manufacturer's approved specification and the recommendations of the supplier of the equipment are suitably considered.

3.2.6.1 *Discussion*—Consideration should be given to ISO/ASTM 52930.

3.2.7 *machine fleet variation, n*—variations within multiple machines of the same model.

3.2.8 *process operational qualification, n*—establishing by objective evidence that process control limits have been sufficiently challenged and result in outputs that meet all predetermined requirements.

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

3.2.10 *process re-validation, n*—establishing by objective evidence that the process under anticipated conditions consistently produces a product that meets all predetermined requirements once specific changes that could sufficiently change a product's performance have occurred.

3.2.11 *process validation, n*—establishing by objective evidence that a process can produce a result or product meeting its predetermined requirements, for example, part cleaning.

3.2.11.1 *Discussion*—Consideration should be given to the difference between machine types, fleet of one or more machines versus a single machine for process validation.

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

3.2.13 *product verification, n*—confirmation by examination and provision of objective evidence that the specified product requirements have been fulfilled, for example, part dimensions.

3.2.13.1 *Discussion*—Verification should include product performance testing for worse-case process and material configuration(s).

3.2.14 *production process, n*—encompasses the end-to-end AM process and associated post processing to manufacture a finished medical device.

3.2.15 *raw material, n*—as-received powder material and blend used to produce the final mechanical and physical properties of the device.

3.2.16 *risk, n*—combination of the probability of occurrence of harm and the severity of that harm.

3.2.16.1 *Discussion*—This definition is derived from ISO 13485:2016 and differs from the definition of "risk" in ISO 9000:2015.

3.2.17 *risk analysis, n*—a listing of all the hazards associated with process and the level of severity, occurrence and detection for each risk and associated failure mode.

3.2.18 *risk assessment, n*—overall process of risk analysis and risk evaluation.

3.2.19 *risk management, n*—systematic application of management policies, procedures and practices aimed at analyzing, evaluating, controlling, and monitoring risk.

[4] Available from U.S. Government Publishing Office (GPO), 732 N. Capitol St., NW, Washington, DC 20401, http://www.gpo.gov.