Designation: F3456 – 22

Standard Guide for Powder Reuse Schema in Powder Bed Fusion Processes for Medical Applications for Additive Manufacturing Feedstock Materials[1]

This standard is issued under the fixed designation F3456; 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.

1. Scope

1.1 This guide provides a concise approach for users of powder bed fusion (PBF) processes to communicate the method(s) in which feedstock powders are controlled throughout the feedstock lifecycle.

1.1.1 Regulatory bodies may require descriptions of used powder reuse schemes in a submission. This is because a medical device's performance can be affected by the condition of the powder feedstock and current regulations are not prescriptive to powder.

1.1.2 This guide is intended for users of both polymer and metal feedstock powders.

1.2 This guide does not cover powder specifications, recycling strategy, blending processes, lot control, or address contamination prevention.

1.3 *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.*

1.4 *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 *ISO/ASTM Standards:*[2]

52900 Additive manufacturing — General principles — Fundamentals and Vocabulary

2.2 *ASTM Standards:*[2]

B213 Test Methods for Flow Rate of Metal Powders Using the Hall Flowmeter Funnel

B214 Test Method for Sieve Analysis of Metal Powders

B215 Practices for Sampling Metal Powders

B822 Test Method for Particle Size Distribution of Metal Powders and Related Compounds by Light Scattering

B964 Test Methods for Flow Rate of Metal Powders Using the Carney Funnel

2.3 *ANSI/AAMI/ISO Standard:*[3]

ANSI/AAMI/ISO 13485 Medical devices — Quality management systems — Requirements for regulatory purposes

2.4 *U.S. Food and Drug Administration:*[4]

21 CFR 820.60 Quality System Regulation — Identification

3. Terminology

3.1 *Definitions:*

3.1.1 Terminology relating to additive manufacturing in Terminology ISO/ASTM 52900 shall apply.

3.2 *Definitions:*

3.2.1 *overflow powder, n*—excess powder that does not remain in the build volume, but instead is deposited into the overflow region of an additive manufacturing machine.

3.2.1.1 *Discussion*—Because of its exposure to the build volume and previously consolidated material, overflow powder is considered used powder in the context of reuse.

3.2.2 *powder lot, n*—a lot as defined in ISO/ASTM 52900, where the feedstock is powder.

3.2.2.1 *Discussion*—The machine user may develop additional naming/labeling conventions if a single powder lot is permanently subdivided between different machines or to keep track of how many times the powder has been reused. The machine user can choose the exact naming convention provided the convention maintains appropriate traceability and does not create ambiguity in the description of the schema.

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

Current edition approved April 1, 2022. Published May 2022. DOI: 10.1520/F3456-22.

[2] For referenced 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 American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

[4] Available from U.S. Food and Drug Administration (FDA), 10903 New Hampshire Ave., Silver Spring, MD 20993, http://www.fda.gov.

3.2.3 *refreshed powder batch, n*—powder blend of used and virgin powder.

3.2.3.1 *Discussion*—If a strategy of refreshing a batch of used powder with virgin powder is adopted, the user's naming convention must retain traceability for both sources of powder and not create ambiguity. Additionally, the exact ratio of the blend is left to the machine user.

4. Significance and Use

4.1 In PBF systems, powder is often reused to increase feedstock efficiency by reducing waste. While in many applications the customer can rely on the manufacturer's validation and verification activities to ensure their PBF process produces parts of the appropriate quality, some medical device regulatory bodies ask for the powder reuse schema to ensure that any effect of powder reuse on final device performance is assessed.[5] The intention of this guide is to provide manufacturers, customers, and regulatory bodies concise terminology to describe powder feedstock reuse schema for PBF using metal or polymer feedstock. Additionally, a well-defined powder reuse schema may reduce the risk of feedstock contamination and associated defects within the manufacturer's quality management system. Each schema represents a broad reuse strategy and is intended to be used as the starting point in describing a powder strategy to customers and regulatory bodies. While the focus of this guide is for medical applications, the schema referenced can be used for non-medical applications.

5. General Considerations

5.1 *Traceability*—Traceability/naming of materials is a requirement on the quality system of medical devices manufacturers marketing their devices in the United States, regulated under 21 CFR 820.60 and as outlined in Section 7.5.9 of ANSI/AAMI/ISO 13485. Other industries may have similar material traceability requirements. Whether a single lot of virgin powder, or multiple lots of blended re-used powders, specifics of such naming conventions is the responsibility of the machine user.

5.2 *Sieving*—Sieving of virgin powder is often necessary before loading into the material hopper/powder bed fusion machine to prevent larger particles from interfering with the powder spreading process. However, there could be instances where material handling/contamination concerns prevent the use of sieving.

5.3 *Powder Storage*—Whenever powder is stored or handled external to the machine, procedures should be validated that prevent feedstock contamination during blending, sieving, and container transfer.

5.4 *Used Powder*—Used powder can have different process exposure levels (for example, proximity to energy source, build chamber environment, overflow bins) that can affect powder properties. The different exposure levels from part cake, overflow, and powder feed bin may result in material that has different thermal history and should be assessed by the machine user to ensure the different conditions do not adversely affect final product performance.

6. Powder Reuse Schema

6.1 No refreshing with virgin powder.

6.1.1 *No Reuse*—Virgin powder is loaded into the PBF powder feed bin which produces used powder during the build cycle(s). The used powder is then marked as unsuitable for reuse or discarded, or both as shown in Fig. 1.

6.1.2 *Discrete Reuse*—Virgin powder is loaded into the PBF powder feed bin. Used powder from all sources (part cake, overflow, etc.) is reclaimed and stored in accordance with standard storage procedures. When there is no longer sufficient virgin powder feedstock to replenish the bin with enough powder to complete an additional build cycle, the used powder is sieved, blended with the remaining material from the powder feed bin, and loaded back into the PBF powder feed bin. Each time the used powder batches are processed in a build cycle a sequential designation ("*n*" in Fig. 2) is applied to track the number of times the powder has been reused. The process repeats until the powder lot is exhausted, there is no longer enough used powder to complete an additional build cycle, or the powder no longer meets the manufacturer's powder requirements as shown in Fig. 2.

6.1.3 *Continuous Reuse*—Virgin powder only is loaded into the PBF powder feed bin. As used powder is generated, it is sieved and loaded back into the powder feed bin. The process repeats until the powder lot is exhausted, there is no longer enough used powder to complete an additional build cycle, or the powder no longer meets the manufacturer's powder requirements as shown in Fig. 3.

6.1.4 *In-process Powder Reuse*—Virgin powder only is loaded into the PBF powder feed bin. During the build process, overflow powder is captured, sieved, and loaded back into the powder feed bin in real-time. As used powder is generated from the build chamber (that is, not from the overflow bins), it is sieved and loaded back into the powder feed bin. The process repeats until the powder lot is exhausted, there is no longer enough used powder to complete an additional build cycle, or the powder no longer meets the manufacturer's powder requirements as shown in Fig. 4

[5] "Technical Considerations for Additive Manufactured Medical Devices: Guidance for Industry and Food and Drug Administration Staff" available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/technicalconsiderations-additive-manufactured-medical-devices-guidance-industry-and-food-and-drug

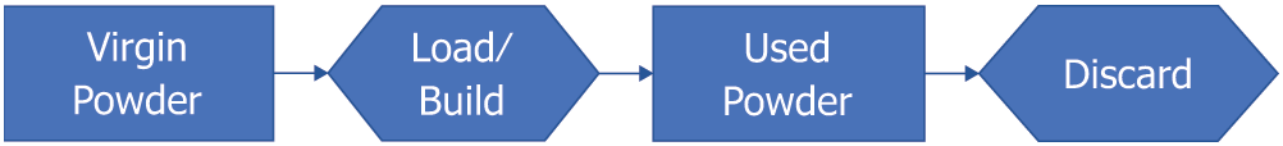

FIG. 1 Example of Powder Reuse Scheme for 6.1.1 No Reuse

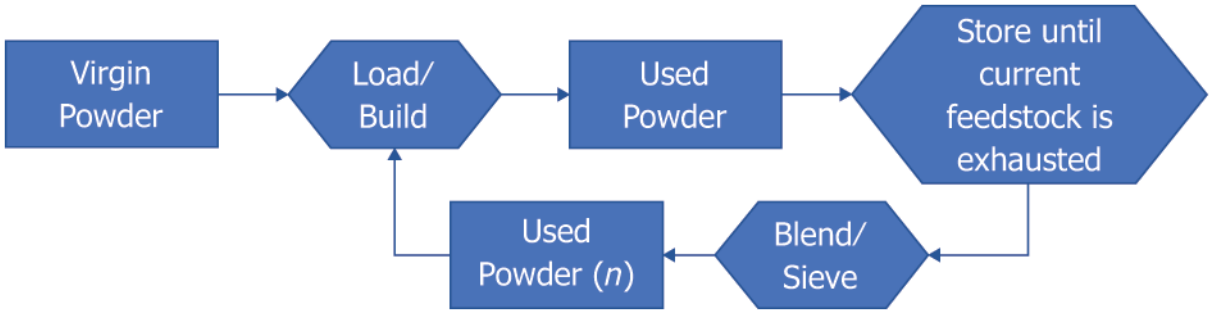

FIG. 2 Example of Powder Reuse Schema for 6.1.2 Discrete Reuse

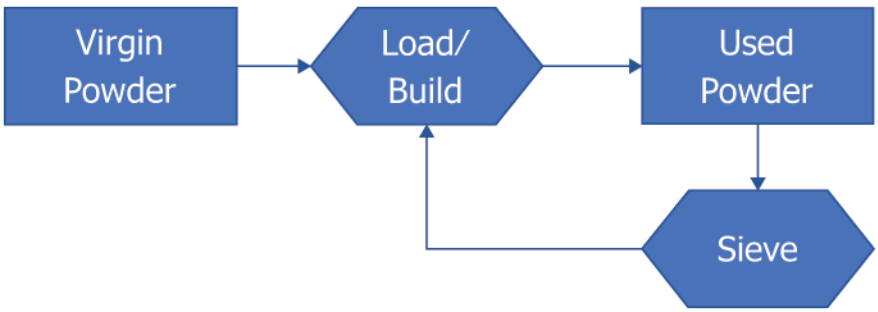

FIG. 3 Example of Powder Reuse Schema for 6.1.3 Continuous Reuse

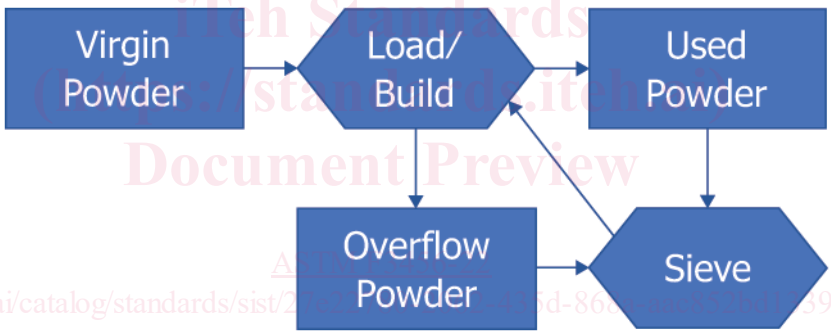

FIG. 4 Example of Powder Reuse Schema for 6.1.4 In-process Powder Reuse

6.2 *Refreshing with Virgin Powder:*

6.2.1 *Continuous Refreshing with Virgin Powder*—Virgin powder is loaded into the PBF powder feed bin. As used powder is generated it is sieved and then blended with virgin powder at the manufacturer's validated pre-specified ratio and then loaded back into the powder feed bin. The process repeats until the powder lot is exhausted, there is no longer enough virgin or used powder blend in the pre-validated and pre-specified ratio to complete an additional build cycle, or the powder no longer meets the manufacturer's powder requirements as shown in Fig. 5.

6.2.2 *Use of Blended Virgin/Used Powder*—A previously prepared blend of virgin and used powder is loaded into the PBF powder feed bin. To generate used powder, a first run is usually generated by loading the powder into the build chamber and heating the build chamber to the build temperature for that feedstock without building any parts. Used powder from the PBF process typically is stored outside the machine until there is no longer sufficient initial virgin/used powder blend in the machine to complete the build cycle. Used powder is sieved and blended with virgin powder to create a new virgin/used powder blend, which is then loaded into the PBF powder feed bin. The process repeats until the powder lot is exhausted, there is no longer enough virgin or used powder blend in the pre-validated and pre-specified ratio to complete an additional build cycle, or the powder no longer meets the manufacturer's powder requirements as shown in Fig. 6.

NOTE 1—The ratio of virgin to used powder is generally determined during the design verification process for the specific medical product.

NOTE 2—This method is generally used when the virgin material does not print well or the printing performance discrepancy between the virgin and used powder blends is too great to manage.

6.2.3 *Continuous Reuse While Replenishing with Virgin Powder*—Virgin powder only is loaded into the PBF powder feed bin. As used powder is generated it is sieved and loaded back into the PBF powder feed bin. After a certain number of builds (*n*), sieved virgin powder is loaded into the PBF powder feed bin, after the used powder has been added. The process repeats until the powder lot is exhausted, there is no longer enough used powder to complete an additional build cycle, or