TOWARDS A STANDARD PROCEDURE FOR THE QUALIFICATION OF METAL LASER POWDER BED FUSION EQUIPMENT IN THE AEROSPACE INDUSTRY USING FUNCTIONAL MODELS

D.W. Gibbons[1*] & A.F. van der Merwe[2]
[1]Department of Industrial Engineering
Stellenbosch University, South Africa
18276342@sun.ac.za

[2]Department of Industrial Engineering
Stellenbosch University, South Africa
andrevdm@sun.ac.za

ABSTRACT

This paper aims at proposing a Laser Powder Bed Fusion qualification procedure for use in the aerospace industry. Equipment qualification techniques are investigated along with the challenges currently faced when qualifying Laser Powder Bed Fusion machines. After which the qualification procedure is developed and modelled using systems engineering principles to fulfil the requirements of the aerospace industry. This procedure identifies the chronological steps required for qualification from equipment installation to pre-production readiness and identifies the relevant industry standards, required documentation and responsible persons at each step.

[1] The author was enrolled for an M Eng (Industrial) degree in the Department of Industrial Engineering, Stellenbosch University
[2] The author is an associate professor at the Department of Industrial Engineering, Stellenbosch University
*Corresponding author

1. INTRODUCTION

Qualification of metal Laser Powder Bed Fusion (LPBF) is currently a focus area of research and development in both the additive manufacturing (AM) and aerospace fields [1]. Qualification is a broad term that can address various areas of the supply chain including designs, products, materials, processes, facilities, machines or equipment and can be formally defined as the "process of ensuring suitability to meet functional requirements (design intent) in a repeatable manner" [1]. Qualification of LPBF equipment is the basis on which the proceeding qualification processes are performed and it is, therefore, an essential part of ensuring high quality and ultimately certifiable parts are manufactured. There exist standards for the acceptance inspection of LPBF equipment for aerospace application and for assessing system performance and reliability, although there are currently no standards methods for LPBF equipment qualification for aerospace applications [2][3]. As LPBF is a fairly new manufacturing special process, it is essential to qualify both the machine or equipment and then the process [4]. This paper, therefore, aims at proposing a standard procedure for the qualification of LPBF equipment for aerospace by leveraging equipment qualification procedures traditionally applied in the medical device and pharmaceutical manufacturing industries and subsequently by the ASTM F3434 guide for AM equipment [5].

2. METHODOLOGY

The methodology applied in this paper follows a model-based systems engineering approach (MBSE) with elements of Functions-Based Systems Engineering (FBSE). MBSE, as the name implies, is a systems engineering methodology that involves the "application of modelling to support system requirements, design, analysis, verification and validation activities throughout the system lifecycle phases" [6]. FBSE is an approach that focuses on the functional architecture of a system and can be decomposed into functional elements through functional decomposition following a top-down approach [6]. MBSE is used in contrast to a traditional document-centric systems engineering approach and has various benefits as identified by INCOSE [6]:

- Improved communication amongst system stakeholders.
- Increased ability to manage system complexity.
- Enhanced knowledge capture and reuse.
- Improved product and system quality.
- Improved ability to portray concepts and understanding.

Of the modelling language used for MBSE SysML and IDEF are some of the more popular. SysML, or Systems Modeling Language, is a general-purpose system modelling language based on the UML language and can support various types of models [6]. SysML offers functionality that can be executed and integration with various software packages but does not convey understanding and communication between stakeholders that are not knowledgeable about the language syntax and semantics very well. IDEF, or Integrated Definition, is a family of modelling languages that were initially developed for computer-aided manufacturing applications and based on the Structured Analysis & Design Technique (SADT). IDEF0 is the most often used IDEF language and was developed for functional modelling, other languages such as IDEF1 were developed for information modelling and IDEF3 for process description capture. IDEF0 is used to model the LPBF equipment qualification procedure in this study as it has the functionality to model inputs, outputs, controls and mechanisms in a simple yet functional means. IDEF0 can portray understanding and communicate the functionality of complex systems to stakeholders simply and logically, but also include the necessary information ensuring a quality model is developed. Figure 1 depicts the schematics of an IDEF0 diagram, towards the left. Each aspect of the diagram is assigned a label for traceability to other systems and through the decomposition process. Figure 1 shows how functions and activities sare decomposed from a high-level through to the lower-levels or system elemental level, towards the right as depicted in the IDEF0 standards [7] [8]. Aspects shall transfer between parent and child diagrams but not necessarily between different abstractions of diagrams to reduce unnecessary model complexity.

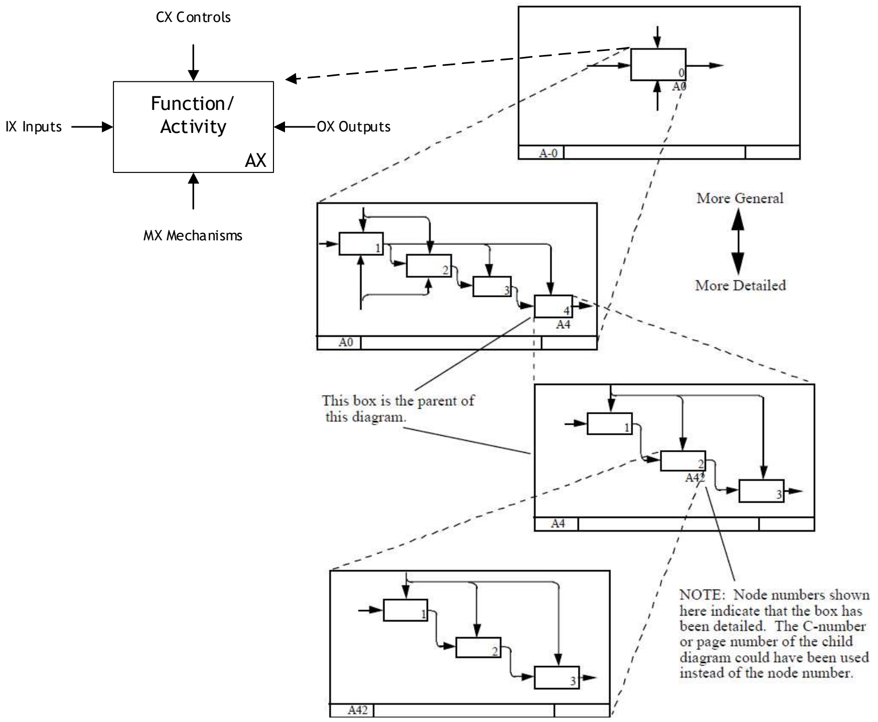

Figure 1: The IDEF0 modelling language and decomposition functionality [7].

The research methods applied in this study consist of a review of the literature and industry best practice documentation and unstructured interviews with local industry experts. The framework of this study consists firstly of a review of the Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) procedure to identify the aims and the benefits of this qualification procedure, secondly, a review of LPBF machine qualification challenges is conducted to highlight why LPBF machine qualification is currently a gap in the industry, lastly, an equipment qualification procedure is proposed utilizing the IQ OQ PQ procedure and systems engineering principles to fulfil these gaps. The proposed procedure and process diagrams aim at defining the LPBF equipment qualification procedure for the scope ranging from equipment acquisition to equipment qualification as part of a generic or baseline production process. This defines the LPBF equipment qualification lifecycle prior to part-specific process qualification. The author notes there are various additional qualification requirements that have an effect on the LPBF equipment qualification such as operator qualification and facility qualification. These have not been addressed within the scope of the paper.

3. EQUIPMENT QUALIFICATION AND THE NEED FOR A STANDARD LPBF EQUIPMENT QUALIFICATION PROCEDURE

Equipment qualification is a prevalent topic within the medical and pharmaceutical industry. Manufacturing practices within these industries are defined by the Good Manufacturing

Practice (GMP) and Good Automated Manufacturing Practice (GAMP) guidelines and enforced by regulatory agencies such as the Food and Drug Administration (FDA) [9]. These guidelines identify the best practices for validating manufacturing machines and equipment. The sequential procedure used to qualify equipment according to these guidelines is the Design Qualification (DQ), IQ, OQ and PQ procedure, this approach is recommended in the industry-agnostic standard guide for LPBF machine qualification ASTM F3434 [5]. This procedure aims at ensuring the equipment has been correctly designed and installed to customer requirements, the operating limits and capabilities are understood and the equipment can reliably produce products of the required quality. Such a qualification procedure shall utilize a team approach whereby the team shall consist of multi-disciplinary members and the relevant stakeholders such as aviation regulatory agency representatives, machine OEM engineers, manufacturing and quality personnel [10]. Although this procedure is not mandated for manufacturing in the aerospace industry, the principles are universal and provide a standard approach to characterizing and controlling manufacturing equipment and processes and provide documented evidence of such as required for the qualification and approval of special processes in the aerospace industry [11].

AM and specifically LPBF equipment qualification is identified as a gap within the industry [1]. There are various reasons why the development of a standard qualification approach is a challenge, some of which include [1]:

- The vast amount of process parameters that need to be understood and controlled.
- Maintenance and calibration are performed by machine OEMs, each having differing procedures.
- Understanding and characterization of machine-to-machine and part-to-part variability.
- Varying manufacturing process configurations.

4. PROPOSED LPBF EQUIPMENT QUALIFICATION PROCEDURE

The IQ OQ PQ procedure provides a guiding framework for equipment qualification but does not define the activities that need to be performed for specific equipment. Therefore, the proposed equipment qualification procedure for LPBF machines follows this IQ OQ PQ procedure as a framework and leverages industry standards to define specific processes and activities required to qualify LPBF equipment. Such a qualification procedure qualifies the LPBF equipment, necessary post-processing equipment and their relevant operating procedures, this is in conformance with the requirements of AWS D20.1/D20.1M [12]. The proposed procedure addresses the full qualification lifecycle with a focus on equipment, requirements for qualification and control of LPBF systems have been reviewed in previous literature. It is noted that the proposed qualification procedure does not negate aerospace industry process validation procedures such as First Article Inspections, as these are part-specific.

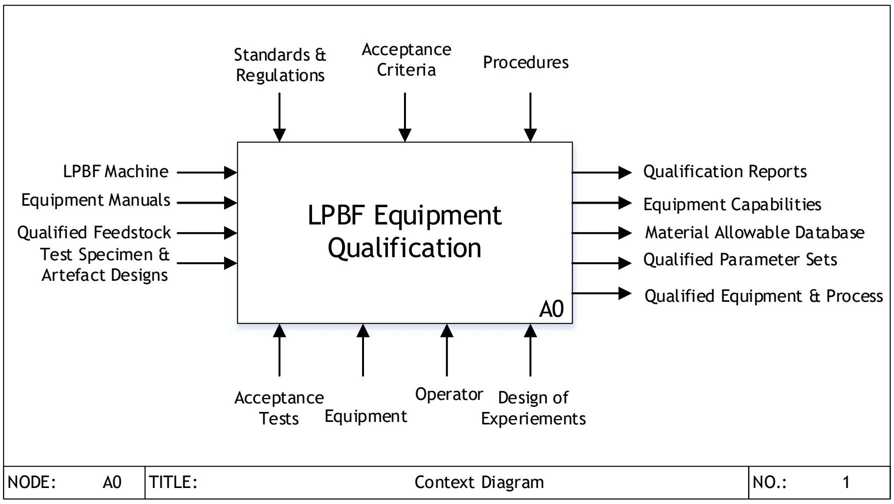

Figure 2: LPBF equipment qualification context diagram (A0 parent diagram).

Figure 2 presents the procedure context diagram, referred to as the A0 parent diagram. As depicted the function of this procedure is LPBF equipment qualification. Figure 3 presents the first decomposition, the A0 child diagram, and provides an overview of the full qualification procedure.

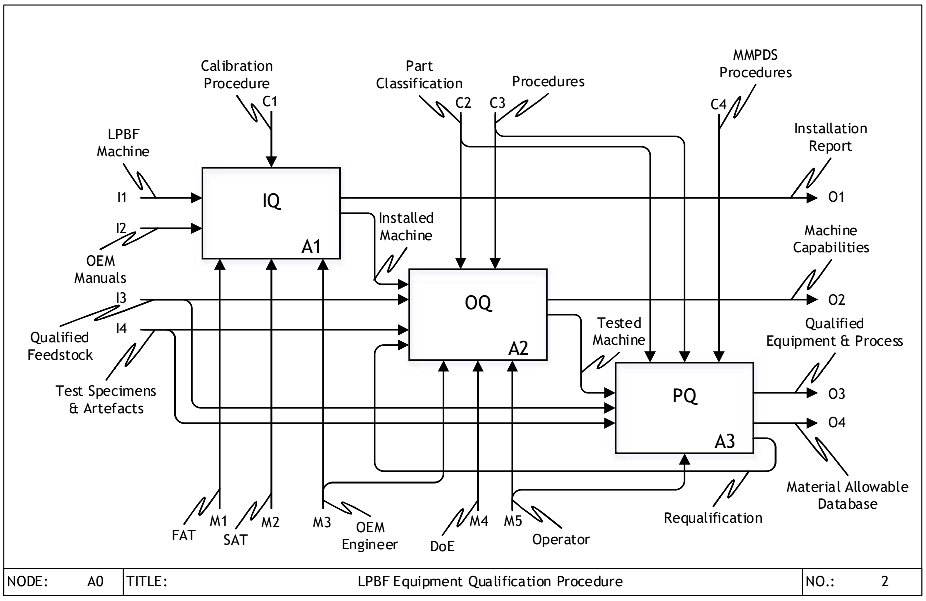

Figure 3: High-level LPBF equipment qualification procedure (A0 child diagram).

DQ has been excluded as this study aims at qualifying standard LPBF machines, DQ is performed solely by the machine OEM. IQ and OQ shall be performed for each critical equipment item within the proposed process, and the PQ is performed on the baseline process as a whole, further part-specific process qualification is required hereafter. A feedback loop has been included for the requalification of equipment. Requalification shall consist of a full OQ and PQ procedure. Requalification criteria are defined by SAE AMS 7003 [13]. Initial equipment calibration occurs during the IQ procedure, although periodic equipment calibration shall be performed and depending on the output of the calibration, may require requalification. Maintenance and calibration shall undergo a formal review to determine the severity and effect of the maintenance performed and decision as to whether requalification is required. Both calibration and maintenance procedures shall be defined as part of the quality management system. Manufacturing assessment methods such as Manufacturing Readiness Level (MRL) and SAE AS 6500 for manufacturing management provide additional means for assessing the maturity of the manufacturing process throughout the qualification procedure and should be applied as guidance for progressing to the next phase of the qualification procedure [14] [15]. Acceptance criteria shall be developed based on the criteria defined by these documents.

The procedure presented in this study consists of three decomposition levels, additional decompositions typically would be addressed by formal procedures, qualification protocols and work instructions.

4.1. Installation Qualification (IQ)

IQ starts at the machine OEMs facility, a factory acceptance test (FAT) is performed following a predefined and agree acceptance test protocol. The machine OEM shall provide evidence that the LPBF equipment is of a production-ready Technology Readiness Level (TRL) during the FAT. It is recommended that a representative from the customer be present during the FAT. The IQ procedure is performed by the machine OEM technician or engineer, with the supervision of the customer. The installation phase consists of the installation of the LPBF machine as well as the installation and configuration of required auxiliary equipment. A prerequisite to installation is facility qualification consisting of a site assessment to ensure the installation environment is fit for purpose. Commissioning involves the integration of equipment and the initial start-up, diagnostics and calibration. The site acceptance test (SAT) follows a similar protocol as the FAT, ensuring the installed system is in accordance with requirements. Both parties are to agree to the SAT, after which a formal IQ report is documented.

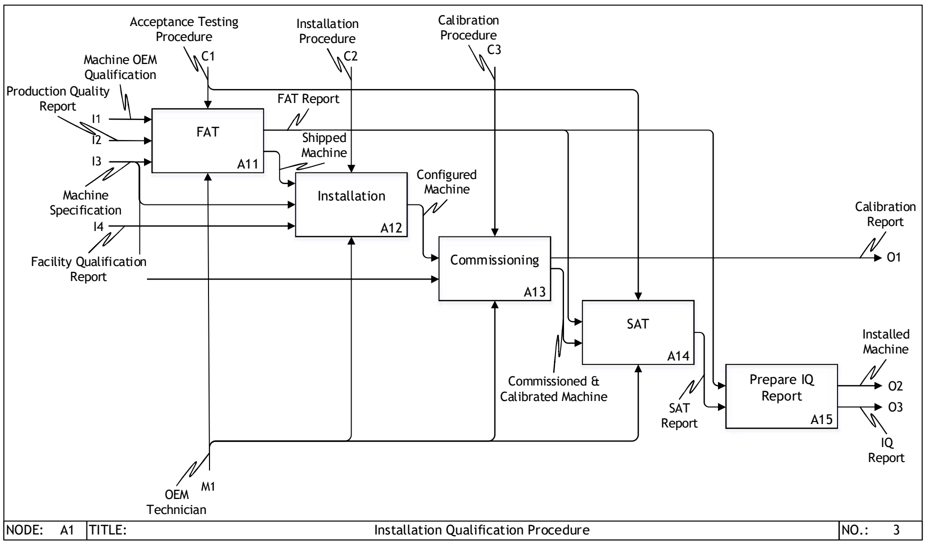

Figure 4: Installation Qualification procedure.

4.2. Operational Qualification (OQ)

The OQ procedure aims at characterizing the LPBF process and determining the machine capabilities. It begins with the lengthy process of developing and validating procedures and protocols for the newly installed equipment. Such procedures shall be in accordance with industry requirements such as SAE AS 9100D and Nadcap AC7110/14 and qualification protocols shall contain acceptance criteria for the OQ and PQ procedures dictated by the required part properties for the part classification the LPBF equipment is being qualified for [16] [11]. Identification of process variables is performed by structured failure modes and effects analysis (FMEA), firstly through a Machinery FMEA (MFMEA) whereby machine-specific failure modes and effects are defined including physical aspects, process parameters and settings of the LPBF machine, such an MFMEA shall be performed for each machine or equipment within the manufacturing process and be maintained in the machine or equipment operating manual, and secondly, as a preliminary Process FMEA (PFMEA) whereby failure modes and effects are defined for the proposed manufacturing process. An Ishikawa analysis may be performed before the FMEAs for initial risk identification. Such techniques shall be performed by a team of experts with the guidance of the machine OEM. Effective FMEAs are required for screening Design of Experiments (DoE) to identify which process parameters have a negligible effect on part quality. The focus shall be on the severity rating of the FMEAs when used for such an application. The Plackett-Burman and Resolution III designs may prove beneficial as a possible screening DoE as these allow a large number of variables to be screened through relatively few experiments [17]. The Plackett-Burman design relies on the effective identification of critical variables and the determination of acceptable levels of such variables, hence the need for effective FMEA analyses performed by experts. If process parameters are not determined internally, such parameters may be provided by the machine OEM, in which case the machine OEM shall provide evidence that sufficient qualification of the parameters has been performed. In both cases, specimens and artefacts are to be manufactured and tested, either to determine the effects of the designed experiments or to verify the parameters provided by the machine OEM on the installed equipment. Such specimens and artefacts shall take into account material anisotropy typically exhibited by LPBF, the AWS D20.1/D20.1M, ISO/ASTM 52941 and ISO 52911-1 provide guidelines for such specimen and artefact development and testing [12][3][18]. Measurement System Analysis (MSA) shall be performed to determine the accuracy and precision of the measurements, such an analysis ensures the results of both the OQ and PQ phases are accurate. Results from the experiments need to be analyzed to determine the optimal parameter sets, this is performed by characterizing the response of the DoEs. The output of the OQ procedure is a report with the LPBF equipment capabilities and optimal unvalidated parameter sets. The generic production process is “frozen” upon the successful completion of the OQ phase. This generic process shall consist of the LPBF process and required standard post-processes such as stress relief and a hot isostatic pressing process and depending on the part classification the process is being qualified for, certain surface finishing processes as well. Each of these processes and equipment shall be subjected to individual qualification similarily to the IQ and OQ procedure defined for LPBF equipment in this paper prior to the generic production process OQ. Requalification is required if acceptance criteria aren’t met during OQ.

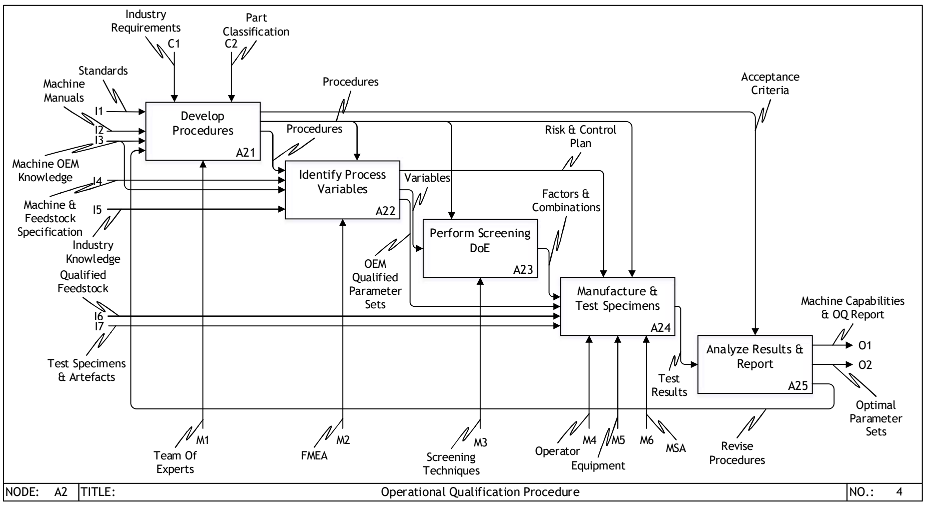

Figure 5: Operational Qualification procedure.

4.3. Performance Qualification (PQ)

The aim of PQ is performance validation under normal operating conditions [10]. For aerospace applications, industry requirements, such as those depicted by the Metallic Materials Properties Development and Standardization (MMPDS) handbook, need to be met [19]. Material allowables may be generated or equivalence to previously generated and approved allowables shall be shown during the PQ phase. The part classification determines the required number of builds from the number of feedstock heats and lots required to qualify the LPBF equipment to a statistical significance. A method to reduce variability in recycled feedstock is proposed elsewhere [20]. These builds are then manufactured and tested, and the results are utilized to perform capability studies. It shall be shown that the data from the PQ builds are within acceptable limits and that the critical variables are controlled effectively. Such data, if conforming, can be used by an authorized design organization to design parts optimized for the LPBF process. These capability studies are continued through regular production. If the results show the process is not in control, a review shall be performed and the OQ procedure revisited. A formal qualification report is prepared upon the successful completion of the PQ phase, this identifies the process, parameter set and equipment, by serial number, that was able to meet the material specification for the part classification in question. The LPBF equipment and generic production process are qualified for the process window characterized during OQ [5]. Upon the successful completion of the PQ phase, the manufacturing process is at an MRL of 7. To advance to an MRL of 8 and beyond, part-specific qualification procedures shall be performed and the manufacturing process is frozen to that specific part.

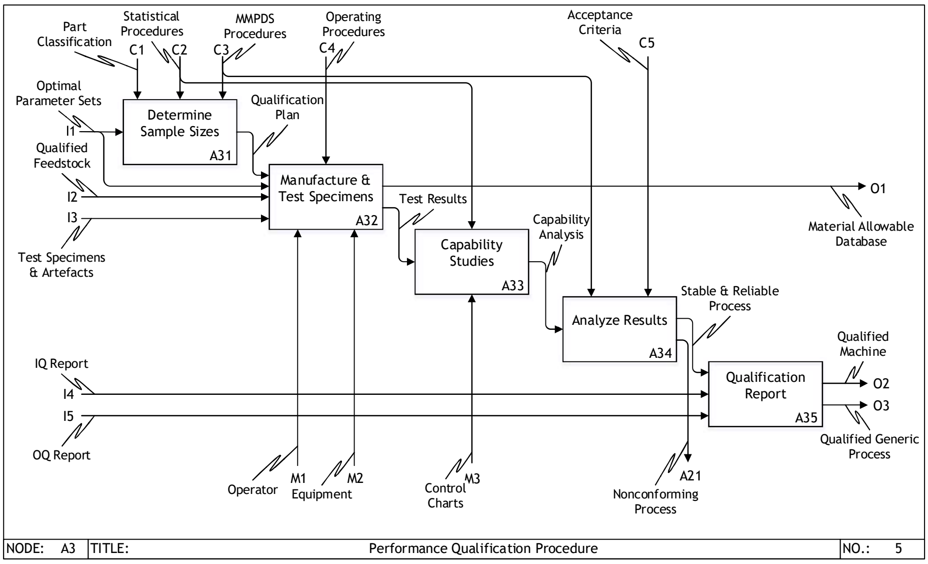

Figure 6: Performance Qualification procedure.

5. CONCLUSION

This paper investigates how industrial machines and equipment are qualified, and the challenges faced when qualifying LPBF equipment. A qualification procedure is then proposed for LPBF equipment within the aerospace industry by leveraging the IQ OQ PQ procedure. The proposed qualification procedure utilizes a model-based systems engineering approach to identify and define the chronological steps towards LPBF equipment and process qualification. Through the formal application of such a procedure, process variability can be reduced and controlled to a level required for the respective part criticality. Additionally, the proposed procedure identifies what documentation needs to be recorded at these steps for certification purposes, who are the responsible persons and what processes and activities need to be performed.

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