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Part 1: Common failure modes used for process risk mapping

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Foreword

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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).

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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, 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).

ISO/ASTM 52954 consists on the following parts, under the general title Additive manufacturing – Qualification principles:

— Part 1: Common Failure modes used for process risk mapping

— Part 2: Specific PBF-LB/M failure modes used for risk mapping[1)]

A list of all parts of the ISO/ASTM 52954 group standard can be found on the ISO website.

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.

1) Under preparation

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Introduction

Additive manufacturing increasingly represents an attractive alternative to conventional manufacturing methods for companies. The trend towards complex parts, decentralized manufacturing and customised products allows economically viable application for a wider area. This applies to an increasing number of serial applications, which pose new requirements and risks to the processes' performance. High quality, safety and risk mitigation requirements need to be fulfilled for components used industrially, especially in regulated industries (e.g., automotive, railway, aerospace, energy, medical). The present lack of standards means that processes and corresponding risk management for the additive manufacturing of parts need to be defined from scratch for each individual case, which entails a high degree of expense, and which permits little transparency and hence little trust amongst stakeholders in the process.

Where industrial parts are produced using additive manufacturing techniques, the manufacturer needs to verify how the applicable requirements are satisfied and that the corresponding risks are eliminated or reduced as low as reasonably practicable.

To this end, the process chain and environment are designed and evaluated in a way that the process quality and resultant part quality remain consistent and reproducible and simultaneously suppress new risks and hazards emerging in or after the process.

The document outlines the relevant areas to establish a process failure modes and effect analysis (pFMEA) / risk management assessment. It supports the implementation of AM as a production method within critical applications and regulated industries, e.g. automotive, rail, aerospace, energy, and medical. This document helps to address the requirements for "risk based" validation approach. While being implemented within risk assessments, the standard assures state-of-the-art quality assured usage of AM, as a production method for safety critical components.

This document aims to outline the risk relevant areas and mitigations as an integral whole (not product specific), which are necessary as a basis for designing processes for high-quality and risk-minimized additively manufactured parts. The criteria defined within the framework of this document supports a basis for fulfilling the requirements for specific products risk management.

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Additive manufacturing — Qualification principles —

Part 1: Common failure modes used for process risk mapping

1 Scope

This document specifies failure mode areas that are applicable to any additive manufacturing (AM) process category.

NOTE 1 Process categories are defined in ISO/ASTM 52900.

It lists examples of state-of-the-art failure modes, which possibly lead to risks within AM parts and equipment. It provides informative examples of corresponding failure effects and mitigation actions.

This document gives guidance to help part manufacturers in their risk management.

This document maps risks of AM processes described in ISO/ASTM 52920.

This document does not cover risks related to:

— specific to environment, health and safety (EHS) issues;

— application specific designs;

— application specific usage of products;

— part specific input and output parameters; and

— specific AM systems and process types.

NOTE 1 Guidance on AM process category specific failure modes will be addressed in other parts of ISO/ASTM 52954, including but not limited to PBF-LB/M, PBF-LB/P, MEX, MJT, BJT, and DED.

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 14971, *Medical devices — Application of risk management to medical devices*

ISO 31000, *Risk management — Guidelines*

ISO/ASTM 52900, *Additive manufacturing — General principles — Fundamentals and vocabulary*

ISO/ASTM 52920:2023, *Additive manufacturing — Qualification principles — Requirements for industrial additive manufacturing processes and production sites*

ISO/ASTM/TS 52930, *Additive manufacturing — Qualification principles — Installation, operation and performance (IQ/OQ/PQ) of PBF-LB equipment*

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3 Terms and definitions

For the purposes of this document, the additive manufacturing terms and definitions given in ISO/ASTM 52900 and ISO/ASTM TS 52930 apply.

For the purposes of this document, the risk-based terms and general definitions given in ISO 31000 and ISO 14971 apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

4 General use of this document

This document enables all part owners and manufacturers to use it for the process risk mapping activities, to support subsequent risk assessments, continuous improvement, validation planning, estimation of manufacturing efforts, and conformity audits. It aims to close the existing gap between general risk management standards, such as ISO 31000 or ISO 14971 (medical), and the know-how gap of existing failure modes of the AM process category and their integrated workflow.

The process map/ flow diagram is a prerequisite to a risk assessment. The process map/ flow diagram will depend on the AM technology and the part/customer requirements. A clear understanding of this flow is needed before staring a risk assessment.

Risk assessment is dependent on many factors and is an on-going process. Risk assessments shall be periodically reviewed and updated as new risks are identified or new controls are implemented.

Potential reasons for risk updates include:

— new facility set up or facility relocation;

— new production line set up;

— process changes;

— new products outside the scope of existing completed pFMEA product families;

— new critical or approval relevant part needs to be risk assessed;

— failure occurrence in the process.

The list of potential AM process failure modes is varied depending on the AM process category in operations. This document outlines a general approach to AM process risk management that is independent of AM process category. AM process category specific risks will be identified in other parts to this document.

Risk assessments provide support to process qualification, as referred to in ISO/ASTM 52920:2023, 7.2 “Scope of Qualification” and 7.3 “Validation planning”.

Risk management, which comprises identification, evaluation, and mitigation of the risks, shall be performed by suitably competent personnel.

The failure mode examples, failure effect or consequence examples and informative risk mitigation examples listed in Annex A are provided for guidance only. They are not exhaustive and do not constitute a mandatory checklist. Those performing the risk assessment shall determine which risks are applicable to the specific activity, product, or project being assessed. Risks that are not relevant need not be included in the documented risk assessment.

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