Guidance Notes for the Certification of Metallic Parts made by Additive Manufacturing

March 2017

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Lloyd's Register

TWI

Contents

These Guidance Notes are intended to be a live document and are subject to change without notice.

Published by Lloyd's Register Group Limited. Registered office (Reg. no. 08126909), 71 Fenchurch Street, London, EC3M 4BS, United Kingdom.

■ *Section 1* Introduction

1.1 Purpose

The purpose of this document is to provide industry with goal-based certification guidelines for the manufacture of metallic parts/components using additive manufacturing (AM), also known as 3D printing.

1.2 General

The basis of the design, manufacture and inspection of any part intended to be manufactured by AM will require a study of the functional requirements of that part. This is because the inspection requirements will be specific to that part and the AM process used.

The outcome of this functional study, together with any requirements within the applicable existing codes and regulations, will define what must be demonstrated in order for the part to be certified.

In the future, as and when prescriptive requirements are developed and established by industry, such considerations will become the norm and be embedded in code or regulatory acceptance criteria. Until then, these goal-based guidelines describe a basis for achieving a design, manufacture and inspection methodology for AM that provides a route for the certification of AM components that is equivalent to the certification of components produced using conventional techniques.

1.3 Scope

The scope of this document is the additive manufacturing of metallic parts using Laser Metal Deposition (LMD) techniques (see Figure 1); and Laser Powder Bed Fusion (PBF) techniques (see Figure 2); and Wire Arc Additive Manufacturing (WAAM) technique (see Figure 3).

Figure 1 Laser Metal Deposition

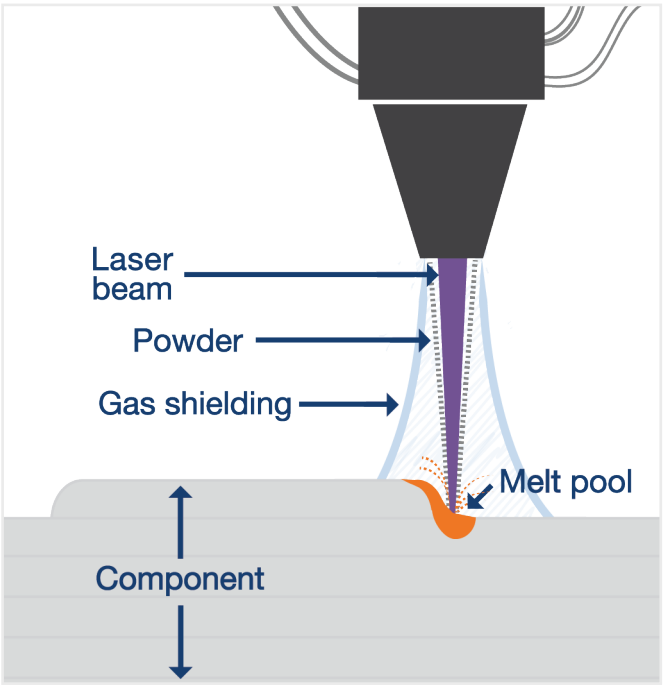


Figure 2 Laser Powder Bed Fusion

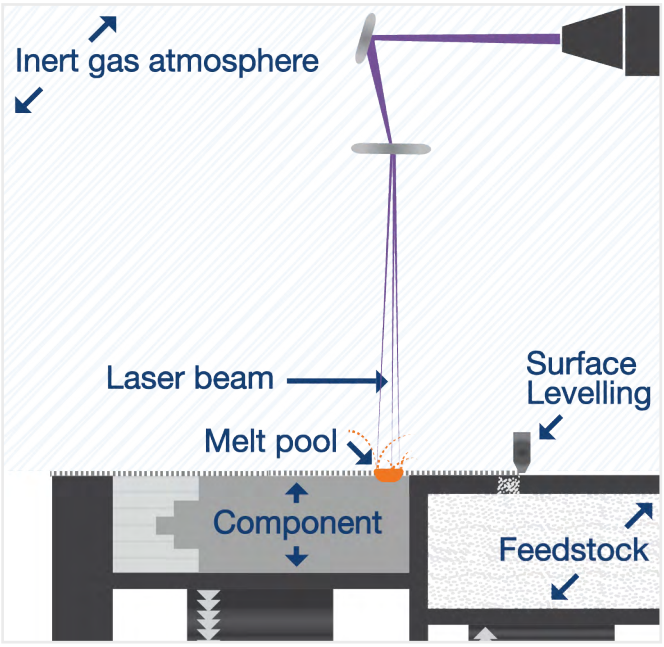
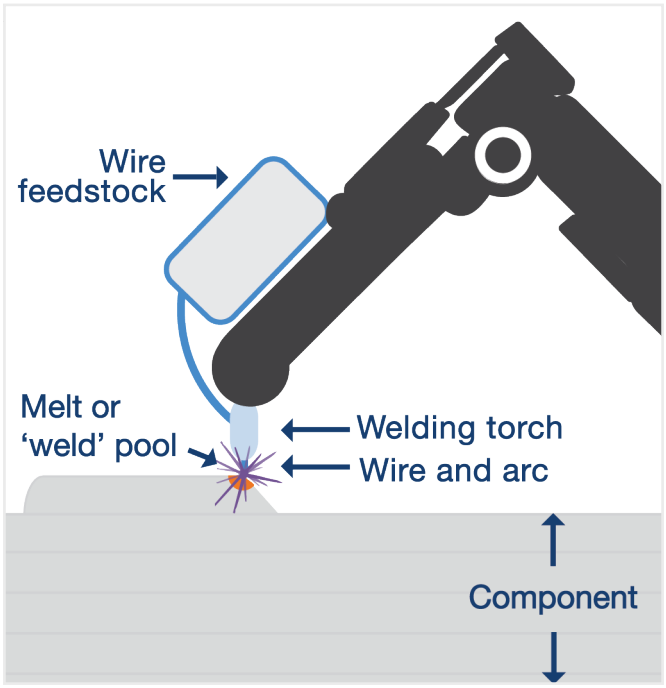


Figure 3 Wire Arc Additive Manufacturing



The use of AM for repair is not within the scope of this document. For guidance on part repair using specific AM techniques (i.e. laser cladding, flame, arc, plasma and High Velocity Oxygen Fuel (HVOF) spraying), refer to Lloyd's Register Materials and Qualification Procedures for Ships Book L, Procedure 15-1.

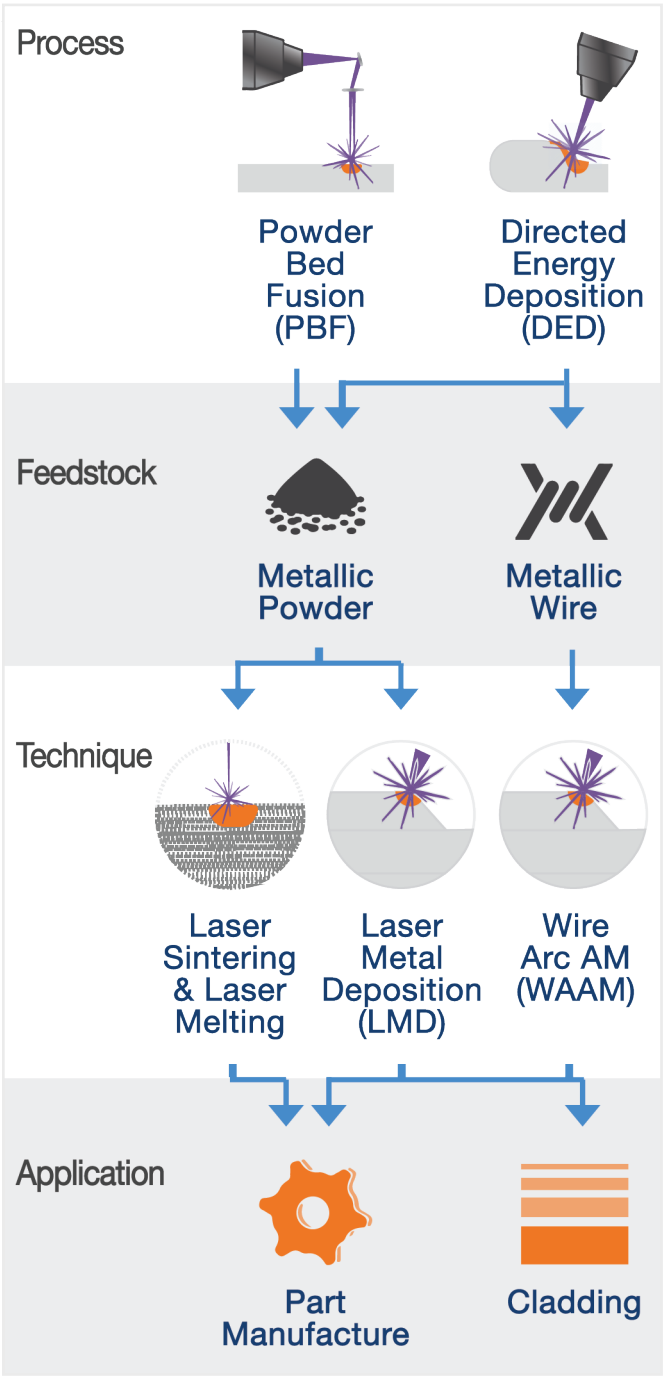
Other AM processes and materials (e.g. non-metallic) may be considered on a case-by-case basis, following special consideration by the Certification Authority.

1.4 Hierarchy and Terminology

Figure 4 illustrates the hierarchy of the AM scope and the primary currently preferred terms (defined within ISO/ASTM 52900:2015).

Other AM processes (defined within ISO/ASTM 52900:2015) are not covered by this document.

Figure 4 Standard terminology for additive manufacturing



■ *Section 2* Abbreviations and definitions

2.1 Abbreviations

3D	Three Dimensional
AM	Additive Manufacturing
AMF	Additive Manufacturing Format
AOR	Artificial Optical Radiation
Ar	Argon
ASME	American Society of Mechanical Engineers
CAD	Computer Aided Design
DED	Directed Energy Deposition
EAI	External Authoring Interface
He	Helium
HIPping	Hot Isostatic Pressing
HVOF	High Velocity Oxygen Fuel
IP	Intellectual Property
ISO	International Standards Organisation
LMD	Laser Metal Deposition
MSDS	Material Safety Data Sheet
NDE	Non-Destructive Examination
NIST	National Institute of Standards and Technology
O_2	Oxygen
OEM	Original Equipment Manufacturer
PBF	Powder Bed Fusion
PPE	Personal Protective Equipment
RPE	Respiratory Protective Equipment
QA	Quality Assurance
STL	Surface Tesselation Language
VRML	Virtual Reality Modelling Language (ISO/IEC 14772-1:1997 and ISO/IEC 14772-2:2004)
WAAM	Wire Arc Additive Manufacturing

2.2 Definitions

3D CAD modelling (solid modelling)	The process most commonly used during design to produce a digital 3D model.
3D scanning (3D digitising)	Method of acquiring the shape and size of an object as a 3D representation by recording x, y, z coordinates on the object's surface and using software to convert into digital data.
Additive Manufacturing (AM)	A process by which digital 3D design data is used to build up a part in layers by depositing material.
Additive Manufacturing Format (AMF)	File format for communicating AM model data including a description of the 3D surface geometry with native support for colour, materials, lattices, textures, constellations and metadata.
Build space	Enclosed volume within the AM system where the parts are fabricated.
Certification Authority	A trusted third party organization (such as Lloyd's Register) that inspects a client's products against a regulatory requirement or specified standards.
Directed Energy Deposition (DED)	Additive manufacturing process in which focused energy is used to fuse materials by melting as they are being deposited.
Feedstock	Bulk raw material supplied to the AM building process.
File format	File format for model data (e.g. STL or AMF) describing the surface geometry of an object as a tessellation of triangles used to communicate 3D geometries to machines in order to build physical parts.
Fusion	The act of joining two or more units of material into a single unit of material.
Laser Metal Deposition (LMD)	Directed Energy Deposition process in which lasers are used to fuse powdered materials by melting as they are being deposited.
Part	Joined material forming a functional element that could constitute all or a section of an intended product.
Porosity	Presence of small voids in a part making it less than fully dense.
Post processing	One or more process steps taken after the completion of an additive manufacturing build cycle in order to achieve the desired properties in the final product.
Powder Bed Fusion (PBF)	Additive manufacturing process in which focused energy selectively fuses regions of a powder bed.
Process parameters	Set of operating parameters and system settings used during a build cycle.
Repeatability	Degree of alignment of two or more measurements of the same property using the same equipment and in the same environment.
Subtractive Manufacturing	Any of the various processes in which material is removed to produce a part of a desired shape and size.

STL	File format for model data describing the surface geometry of an object as a tessellation of triangles used to communicate 3D geometries to machines in order to build physical parts.
Used powder	Powder that has been supplied as feedstock to an AM machine during at least one previous build cycle.
Virgin powder	Unused powder from a single powder lot.
Wire Arc Additive Manufacturing	Additive manufacturing technique where wire is fused using arc melting to underlying layers.

■ *Section 3* Suitability for additive manufacturing

AM is one of many processes that a designer, manufacturer or purchaser may choose for producing components that require certification. When considering whether the use of AM is appropriate the manufacturer shall consider within the context of other manufacturing routes, the potential to meet all applicable requirements (e.g. regulatory, application-specific).

The below criteria shall be considered in the context of determining whether AM is the most suitable process for a given part, and if so, which type of AM:

- Complexity.
- Current situation.
- Lead time.
- Material cost.
- Metallurgical structure.
- Multiple operations.
- Part optimisation.
- Part size.
- Production size.
- Reverse engineering.
- Shipping time and cost.

For further guidance, contact Lloyd's Register or TWI Ltd.

■ *Section 4* Certification approach and activities

Regardless of the AM process adopted, the typical activities that support certification may be categorized into one of the following five stages (see Figure 5):

1. Design.
2. Materials.
3. Manufacturing.
4. Post-processing.
5. Inspection and testing.

Figure 5 Functional stages for certification

It is also recognised that different organisations within the supply chain may perform activities within each of the stages listed above. Therefore, specific certification can be provided for each stage which can reduce the effort required for subsequent part design, material supply and manufacturing activities for subsequent contracts (see Appendix 1 for more information). Using pre-certified organizations in each stage can enable part manufacturers to reduce the cost and lead times for part certification.

■ *Section 5* Design

5.1 General

For parts manufactured by AM, the designer shall establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of parts that meet customer and regulatory requirements.

5.2 Actions to address risks

When planning for the design, manufacture and inspection of parts intended to be manufactured by AM, the organisation shall consider the needs and expectations of the interested parties and the requirements related to quality, environment and health and safety.

The manufacturer shall submit a risk analysis that addresses the following:

- Assurance that the parts intended to be manufactured by AM achieve their intended outcomes.
- Prevention or reduction of undesired effects.

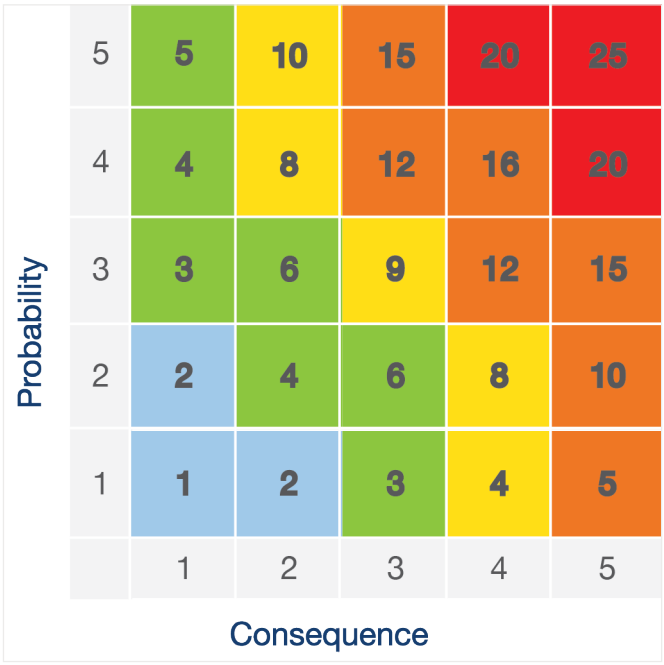
The organisation shall plan actions to reduce or remove these risks, and define how to:

- Integrate and implement the actions into its design, manufacturing and inspection processes.
- Evaluate the effectiveness of these actions.
- Retain appropriate documented information as evidence of competence.

A study shall be undertaken as part of the design activity to determine the possible consequences and probability of part failure. Various risk assessment techniques are available (e.g. refer to ISO Guide 73, ISO 31000 or EN 31010) but frequently a risk matrix is used (see Figure 6 for an example) where the level of risk is determined from the product of consequence and probability. Organisations may have different definitions and thresholds for the level of risk so this study will be reviewed on a case-by-case basis.

Organisations and industries may have different definitions and thresholds for the level of risk (e.g. to safety, business impact, etc.) so this study will be reviewed on a case-by-case basis with consideration of all relevant national and international safety regulations and guidance.

Figure 6 An example of a risk matrix



5.3 Standards and regulations

If a standard used as the basis for design does not include parts made by AM then it must include a clause allowing the manufacturer to demonstrate an equivalent level of safety with alternative materials and alternative methods of design and manufacture. For example, Lloyd's Register Rules allow divergence from prescribed requirements, and where this is proposed, the alternative requirements will be agreed on a case by case basis.

The designer shall consider introducing a suitable design factor (such as that used for cast parts) and the mechanical properties assumed in design must be proved during testing. Provided that the part is manufactured as modelled and meets the requirements specified within the design code, when applicable, then the design may be accepted on that basis.

5.4 Design and development planning

When determining the stages and controls for design and development, the organisation shall consider:

- The nature, duration and complexity of the design and development activities.
- The required process stages, including applicable design and development reviews.
- The required design and development verification and validation activities.
- The entities, authorities and subsequent responsibilities for the design and development process (i.e. customers, users, involvement of an Certification Authority if requested by the end user or required by a code or standard).
- The internal and external resource needs for the design and development of products and services.
- The need to control interfaces between persons involved in the design and development process.
- The requirements for subsequent provision of parts intended to be manufactured by AM.
- The level of control expected for the design and development process by customers and other relevant interested parties.
- The documented information needed to demonstrate that design and development requirements have been met.

5.5 Design and development inputs

When designing for AM, the organisation shall consider the following:

- Functional and performance requirements.
- Any customer quality requirements.
- Information derived from previous similar design and development activities.
- Statutory and regulatory requirements.
- Standards or codes of practice that the organisation has committed to implement.
- Potential consequences of failure due to the nature of the products and services.

Inputs shall be adequate for design and development purposes, complete and unambiguous. Conflicting design and development inputs shall be resolved.

The organisation shall retain documented information on design and development inputs.

5.6 Design and development controls

The organisation shall apply controls to the design and development process to ensure that:

- The results to be achieved are defined.
- Reviews are conducted and documented to evaluate the ability of the results of design and development to meet requirements.
- Verification activities are conducted to ensure that the design and development outputs meet the input requirements (consideration shall be given at the design stage as to how the final part will be inspected and which non-destructive examination (NDE) techniques would be most appropriate, or requested by a specific code or standard).
- Validation activities are conducted to ensure that the resulting parts intended to be manufactured by AM meet the requirements for the specified application or intended use.
- Any necessary actions are taken on potential issues determined during the reviews, or verification and validation activities.
- Documented information of these controlling activities is retained.

Design and development reviews, verification and validation have distinct purposes. They can be conducted separately or in

any combination, as appropriate to the products and services of the organisation.

5.7 Design and development outputs

The organisation shall ensure that design and development outputs:

- Meet the input requirements.
- Are adequate for the subsequent processes for the provision of parts intended to be manufactured by AM.
- Include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria.
- Specify the characteristics and appropriate acceptance criteria of the parts intended to be manufactured by AM that are essential for their intended purpose and their safe and proper provision.

The organisation shall retain documented information on design and development outputs.

5.8 Design and development changes

The organisation shall identify, review and control changes made during, or subsequent to, the design and development of parts intended to be manufactured by AM, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.

The organisation shall retain documented information on:

- Design and development changes (e.g. changes to personnel and/or software used).
- The results of reviews.
- The authorisation of the changes.
- The actions taken to prevent adverse impacts.

5.9 Build layout

The build layout is a fundamental deliverable from the design stage and shall include:

- Location and orientation of part(s) within the build space.
- Locations and orientations of test specimens within the build space.
- Support structures, where applicable, for the part and test specimens.
- Density block.
- Powder capsule (only for Laser PBF, see Section 7.2 for more information).
- Reference and version markings for traceability and control purposes. Where a requirement for marking is not specified in a code or standard, these (and additional) markings may be specified as a requirement based on agreement between the manufacturer, the purchaser and the Certification Authority when appropriate.

5.10 Software translation

The translation of the 3D Computer Aided Design (CAD) model into build machinery software requires careful consideration of various factors including:

- Format of CAD model and build model files.
- Respective coordinate systems at all data import and export stages.
- 3D model export translation accuracy, especially with respect to critical features.
- The impact of software updates on the translation of legacy parts.

In situations where the model is produced by one organisation (designer) and provided to a separate organisation to produce the actual part (manufacturer), it is the responsibility of the organisation that provides the model file to ensure that the file translation is accurate, unless otherwise agreed with the manufacturer.

For further information, refer to ISO 17296-4 Additive Manufacturing General Principles Part 4 Overview of Data Processing.

■ *Section 6* Materials

6.1 Powder feedstock

6.1.1 General

Powder feedstock is hazardous (see Appendix 2 for more information).

There are various powder properties that affect process parameters (e.g. chemical composition and size distribution) and it is therefore very important to control the selection, storage and testing of powder feedstock to a single batch level.

Surplus powder feedstock must always be disposed of safely in compliance with national/international laws and regulations.

6.1.2 Selection

The following information shall be provided to demonstrate control and traceability:

- Powder supplier contact information.
- Packing date.
- Unique identification of the powder (batch number).
- Product description (i.e. material name and grade and/or trade name, if applicable).
- Process used for melting/ producing the powder (e.g. vacuum induction melting (VIM) with argon gas atomisation).
- Packaging and storage instructions (specifying maximum oxygen content).
- Material Safety Data Sheet (MSDS).

The following parameters shall be determined through testing of samples taken from the powder batch. Tests shall be carried out to a relevant national or international standard where available. A suitable sampling procedure (e.g. ISO 3954) shall be used that includes:

- Chemical composition (including crystalline phases and test methods).
- Thermal characteristics (melting temperature).
- Particle size and distribution evaluation method and results (e.g. by sieving or laser diffraction). Content outside the specified range shall be reported.
- Characteristic density (i.e. apparent density, tap density or skeletal density).
- Powder flow properties (e.g. using a Hall Flowmeter as per ISO 4490).
- Description of morphology (e.g. ISO 9276-6).
- Oxygen content.

If any of the required information is not available on the powder material certificates from the powder vendor then further testing shall be conducted by the manufacturer to determine the missing information.

For further information, refer to ISO 17296-2 Additive Manufacturing General Principles Part 2 Overview of Process Categories and Feedstock.

6.1.3 Storage

Powder feedstock storage shall be in accordance with the powder vendor's instructions, and also include:

- Keep feedstock in separate, labelled, sealed containers in a designated dry storage area.
- Prevent contamination between different feedstock and different batches of the same feedstock, especially when transferring powders from one canister to another vessel.
- Prevent the inadvertent mixing of virgin and used feedstock.

6.1.4 Powder recycling/re-use

Due to the inert environment within a Laser PBF machine the powder feedstock may be sieved and reused.

The number of times laser powder bed feedstock is reused shall be tracked and the recycled powder shall be tested and validated against the original incoming powder specification before re-use. The checking procedure shall be sufficiently frequent to eliminate the risk of unsuitable feedstock being used during manufacturing.

Reused powder feedstock shall never be used in the LMD process but may be used for set-up procedures only.

6.2 Wire feedstock

6.2.1 General

Wire feedstock does not often need special handling precautions to be taken for health and safety reasons, however, poor handling can lead to problems arising in the manufactured components.

Surplus wire shall be disposed of properly in compliance with local/national laws and regulations.

6.2.2 Selection

Wire feedstock shall be selected to reflect the chemistry and physical properties required of the completed part. The following information shall be provided to demonstrate control and traceability:

- Wire supplier contact information.
- Packing date.
- Unique identification of the wire (batch number).
- Product description (i.e. material name and grade and/or trade name (if applicable), diameter, weight and spool size).
- Packaging and storage instructions.
- MSDS.

For further information, refer to ISO 17296-2 Additive Manufacturing General Principles Part 2 Overview of Process Categories and Feedstock.

6.2.3 Handling and storage

Wire feedstock shall be handled in accordance with manufacturers guidelines, but in general the following shall be observed:

- Keep feedstock in original, sealed packaging prior to use, clearly labelled in a designated dry storage area. This is particularly important for cored wires, whether folded or tubular, as atmospheric contaminants can be absorbed into the core of the wire and adversely affect the deposit quality.
- Take steps to eliminate contamination of packaging and wire by water, oil, grease or any other compound which may adversely affect the surface quality of the wire, or cause poor feeding of the wire through the system.
- Wire which is, or is suspected to be, contaminated cannot be reclaimed and must be discarded.
- When opening packaging and mounting into the AM facility, clean gloves shall be worn to prevent contamination of the wire during handling and feeding through wire handling systems.
- Any protective covers on the WAAM system shall be closed to limit contamination during operation.
- Any unused wire shall be returned to its original packaging and sealed in an inert environment if possible) immediately on completion of the part build and returned to the storage areas.

■ *Section 7* Manufacturing

7.1 Overview of additive manufacturing methods

7.1.1 Additive manufacturing system

Adequate procedures, for example standard operating procedures and part specific work instructions and risk assessments shall be provided to ensure the quality of the final part.

Detailed, relevant, site-specific test procedures and installation, operating and maintenance instructions (in line with the requirements of the AM system OEM) shall be provided to the Certification Authority for review.

The procedures shall include all necessary information including the frequency of:

- Preventative maintenance.
- Performance tests.
- Calibration.

It is recognised that build parameters do not transfer directly between different AM machines and further testing would be required if plans were made to produce previously certified parts on a different AM machine. Taking laser-based AM systems as an example, the following list provides an example of some characteristics that vary between machines, thus leading to different results:

- Laser beam profile.
- Laser behaviour (e.g. possible loss of energy).
- Particle flow characteristics.

7.1.2 Auxiliary systems

The purity of the gas used for shielding is an important process parameter, which can be determined from the gas quality certificate. Gas flow rate (and direction on some AM systems) are also key parameters to be controlled and reported.

Selection and maintenance of the gas delivery system (including pipework) shall consider gas purity and avoidance of contamination.

7.1.3 Laser Metal Deposition process parameters and effects

Understanding, control and traceability of the following parameters shall be demonstrated:

- Laser (e.g. power at workpiece, spot dimensions).
- Nozzle (co-axial, 3-beam or side-feeder).
- Traverse speed.
- Stand-off distance (i.e. distance between nozzle tip and surface).
- Shielding gas (e.g. Ar or He, gas flow rate and direction).
- Heat input and cooling characteristics.

- External environment controls (e.g. temperature, humidity).
- Powder feedstock (particle size range and distribution, morphology, feed rate, flow rate, deposition rate).
- Laser absorption/reflectivity (e.g. the substrate material may require shot-blasting to reduce reflectivity).
- Control of baseplates (e.g. baseplate material selected for build; cleanliness of baseplate).

Possible effects that may occur due to choice of process parameters, and which may be reduced or eliminated by optimisation of process parameters:

- Distortion.
- Contamination (with different powder or oxygen contamination).
- Lack of repeatability/consistency.
- Inconsistent results when transferring process conditions to different geometries.
- Excessive/insufficient dilution with substrate.
- Porosity (e.g. due to certain powder morphology and alloy selection).
- Cracking (various types and conditions of cracking; pre-heat required for crack-sensitive materials).
- Surface finish (may require machining - considered as near net shape).

7.1.4 Laser Powder Bed Fusion process parameters and effects

Understanding, control and traceability of the following parameters shall be demonstrated:

- Laser (e.g. power, spot dimensions, exposure time, focus position).
- Scanning strategy (e.g. scan speed, layer thickness).
- Point distance (i.e. distance between successive laser spots).
- Hatch distance and conditions (i.e. shift between tracks in the plane of the beam scanning and track distance).
- Laser absorption/reflectivity (e.g. the substrate material may require shot-blasting to reduce reflectivity).
- Build environment controls (e.g. inert gas, build platform pre-heat temperature, build space temperature and pressure, re-coater blade).
- External environment controls (e.g. temperature, humidity).
- Powder feedstock (e.g. particle size range and distribution, morphology).
- Control of baseplates (e.g. baseplate material selected for build; cleanliness of baseplate).

Possible effects that may occur due to choice of process parameters, and which may be reduced or eliminated by optimisation of process parameters:

- Porosity.
- Lack of fusion.
- Balling (defect where small spheres form leading to discontinuities in the fusion path).
- Cracking.
- De-lamination.
- High residual stresses (influence the dimensional accuracy of a part and the risk of cracking).
- Difficulty achieving repeatability and accuracy.
- Contamination (typically caused by change of powder and/or oxygen contamination).
- Surface finish (may require machining - considered as near net shape).

7.1.5 Wire Arc Additive Manufacturing process parameters and effects

Understanding, control and traceability of the following parameters shall be demonstrated:

- Manufacture of consumables.
- WAAM process and positions.
- Technique (e.g. weaving, multiple wires).
- WAAM consumables, including any flux and shielding gas.
- Control of consumable (e.g. drying conditions).
- Chemical composition of deposit.
- WAAM parameters.
- Preheat and interpass temperatures.
- Cleaning between layers and inspection during production.
- Control of baseplates (e.g. baseplate material selected for build; cleanliness of baseplate).
- Post-production heat treatment.

Possible effects that may occur due to choice of process parameters, and which may be reduced or eliminated by optimisation of process parameters:

- Distortion.
- Contamination.
- De-lamination.
- Cracking.
- Surface finish.
- Porosity.
- Inclusions.
- Lack of Fusion.
- Formation of unfavourable microstructures.

7.2 Control of production

7.2.1 All additive manufacturing systems

The organisation shall implement production of AM parts under controlled conditions. Controlled conditions shall include, as applicable:

- The availability of documented information that defines:
  - The characteristics of the products to be produced.
  - The results to be achieved.
  - The AM machine model and firmware revision used.
- The availability and use of suitable monitoring and measuring resources.
- The implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products have been met.

- The use of suitable infrastructure and environment for the operation of processes (i.e. control of any system, process or software that is required to manufacture the part to the necessary level of quality and meet the client requirements).
- The appointment of competent persons, including any required qualifications.
- The validation, and periodic revalidation, of the ability to achieve planned results of the processes for production, when the resulting output cannot be verified by subsequent monitoring or measurement.
- The implementation of processes and procedures to prevent human error.
- The implementation of release, delivery and post-delivery activities.
- The implementation of a risk-based maintenance plan.

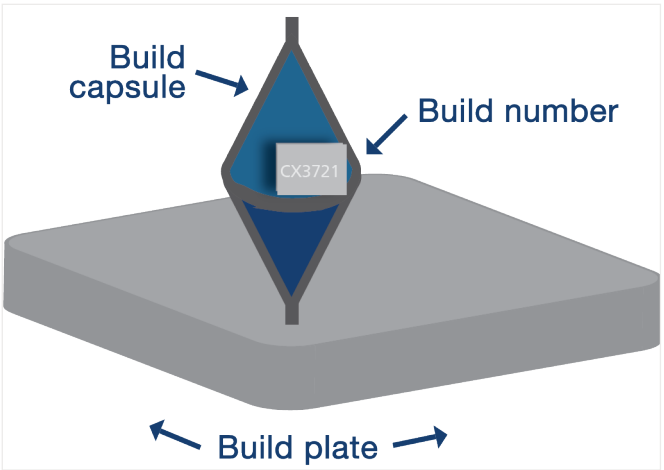
7.2.2 Additional controls for Laser Powder Bed Fusion systems

It is considered good practice to include the following on a Laser PBF build:

- Density block (which can act as the first notification of potential issue during build).
- Powder capsule to be retained for future reference of the powder used during a particular build.
- One set of tensile test specimens to be retained for future reference of the as-built material properties.

A sample of unfused powder feedstock from each powder bed fusion build shall be preserved for future investigation purposes, such that a sample of the actual powder used for any particular build remains available for testing. Powder shall be preserved in an airtight capsule in each build (see Figure 7 for more information). This capsule shall be sized such that it will contain sufficient unfused powder for the relevant powder characterisation to be carried out. This capsule shall be marked with the build number and shall be stored for a specified period of time that has been agreed between the manufacturer and customer and, if applicable, the Certification Authority.

Figure 7 Example diagram of sample powder feedstock capsule



Any non-conformities detected at this stage shall be reported and agreed with the customer and, where applicable, the Certification Authority before continuing (see Section 9.5 for more information).

7.3 Training and qualifications

The quality of parts manufactured by AM techniques is very dependent on the training and skill of personnel.

Records shall demonstrate necessary qualifications and/or competence in the AM process of personnel by presenting a training record, which includes but is not limited to the following:

- Recognised AM audit scheme that includes competency assessment of personnel (e.g. NADCAP).
- Training certificates.
- On-the-job training records.
- Documented experience.
- Evidence of health and safety awareness commensurate with the risk (See Appendix 2 for more information).

■ *Section 8* Post-processing

To achieve the required material properties and final condition of the part, other processes may be necessary following the build, according to material, code and application requirements.

Consideration shall be given to the removal of supports and any necessary machining operations to ensure that they do not have a detrimental effect on the integrity of the part.

Residual stresses shall be considered and measures such as stress relief heat treatment shall be undertaken to ensure that stresses are reduced to an acceptable level or alternatively full heat treatment may be required to achieve the material properties. Hot Isostatic Pressing (HIPping) may also be required to densify the product and remove internal voids or micro shrinkage.

The same post-processing activities shall be applied to test samples as are applied to the manufactured part.

Documentary evidence of the procedures performed and equipment used (for example furnace chart) shall be retained.

■ *Section 9* Inspection and testing

9.1 General

To ensure repeatability, accuracy and consistency when producing AM parts (either LMD, Laser PBF or WAAM), the selected testing and inspection regime must be sufficiently rigorous to take into account the criticality of the part and the potential impact of any lack of repeatability of the AM technique.

The selected design code will drive the quality level required, which will establish the critical defect (indication) size, and therefore, which NDE methods are appropriate. If considered necessary, destructive testing might also be applied. The final selection of NDE methods shall consider the complexity of the part, the criticality of the application, and any inspection limitations.

The inspection shall include the following procedures as a minimum:

- 100% visual examination.
- 100% dimensional examination.

The acceptance criteria specified shall consider all reasonably foreseeable load cases (e.g. if the part is subject to dynamic loading, the fatigue performance shall be specified with the acceptance criteria).

The manufacturer shall retain manufacturing records (job control records), along with testing and inspection reports.

For powder processes, the part shall be removed from the build machinery with any excess powder removed, and the part cleaned before inspection. Inspection by a Certification Authority shall not commence until all post-processing is complete.

Parts manufactured by AM may be susceptible to post manufacture distortion and cracking. Therefore, all dimensional checks and NDE shall only be undertaken after any post-processing requirements (e.g. heat treatment) are carried out. This shall be defined in the component build specification procedure. If heat treatment (or other stress mitigation measures) are not specified, dimensional checks and NDE shall only be undertaken once the part is no longer subject to post manufacturing effects (e.g. after a suitable cooling period, which is dependent upon part and material).

For further information, refer to Sections 4 and 5 of ISO 17296 3 Additive Manufacturing General Principles Part 3: Main Characteristics and Corresponding Test Methods.

9.2 Surface finish

It is often necessary to modify the surface finish of AM parts, especially if a specific roughness is required (e.g. to be compatible with a gasket).

The designer shall specify the surface finish requirements of the part and select suitable post processing operations to achieve the required finish.

9.3 Mechanical testing

Mechanical testing shall be undertaken on test specimens and the final product, as required. Mechanical testing requirements will be specific to the part geometry and application and are therefore to be agreed with the Certification Authority.

Test specimens shall be representative of the part, taking into account mechanical properties and geometry. Consideration shall also be given to minimum and maximum feature size within the part and the build orientation.

For further information, refer to Sections 4 and 5 of ISO 17296-3 Additive Manufacturing General Principles Part 3: Main Characteristics and Corresponding Test Methods. Also refer to the appropriate design code for the test requirements specific to the application. For further information, refer to NISTIR 8005 Applicability of Existing Materials Testing Standards for Additive Manufacturing Materials.

9.4 In-service inspection

The frequency of in-service inspection will align with standard practice within existing procedures but may be enhanced based upon:

- Criticality (see Section 5.2 for more information).
- Any test or inspection limitations identified in the part during previous NDE examinations.
- The geometry and stress distribution.
- The maturity of the AM technique at the point in time of manufacture.
- Whether continuous condition monitoring is carried out.

9.5 Non-conformance

9.5.1 Control of non-conforming items

Defects and imperfections shall be agreed with the customer and, where applicable, the Certification Authority.

To prevent use or shipment, the manufacturer shall establish and maintain procedures to ensure the identification and segregation of all non-conforming materials, parts or work.

Control shall provide for evaluation, documentation for rework and re-inspection or disposal of non-conforming items and for notification to the source from which they came.

9.5.2 Acceptance of deviations

Acceptance of deviations and concessions for use shall follow a documented procedure which ensures that all aspects of the proposals are considered, including an engineering assessment of the effects of the proposed deviations on the safety, function, life expectancy, interchangeability or appearance, of the final product.

Following this assessment, acceptance by the manufacturer, the customer and, where applicable, the Certification Authority, shall be confirmed and recorded in the Manufacturing Plan.

9.5.3 Corrective and preventive action

The manufacturer shall establish and maintain documented procedures for implementing corrective and preventive action to eliminate the cause of actual or potential non-conformities. Corrective or preventive action shall be appropriate to the magnitude of the problem. The manufacturer shall implement and record any change in the documented procedures resulting from corrective and preventive action.

The procedures for corrective action shall include:

- The effective handling of customer complaints and reports of product non-conformities.
- Investigating the cause of non-conformities and recording the results of the investigation.
- Applying controls to ensure that corrective action is taken and that it is effective.

The procedures for preventive action shall include:

- The use of appropriate sources of information (e.g. processes and work operations, concessions, audit results, quality records, customer complaints) to detect, analyse and eliminate potential causes of non-conformities.
- Determining the procedure to prevent non-conformities.
- Initiating preventive action and applying controls to ensure that the action is effective.
- Ensuring that relevant information on actions taken, including changes to procedures, is submitted for management review.

■ *Section 10* Documentation

A 'Manufacturing Plan' is required for each AM part design and this shall contain all the information required to produce that part. The manufacturer shall compile and retain the Manufacturing Plan, which shall consist of:

- Technical documentation relating to part(s):
  - A description of the product(s) with which this application for approval is concerned.
  - Applicable specifications, standards, codes, regulations, etc.
  - Engineering drawings/models used for manufacture (CAD).
  - Applicable calculations (if required by regulation(s) or code(s)).
  - Material information (listed in Section 6).
  - Installation, operation and maintenance instructions (if applicable).
- Facility documentation:
  - An outline description of the relevant manufacturing plant and equipment (including details of geographical location):
    - major items of equipment used for additive manufacturing;
    - for powder processes, powder inspection and recycling equipment (e.g. sampling and sieving equipment);
    - heat treatment facilities;
    - destructive and non-destructive examination facilities;
    - facilities for chemical analysis, metallurgical and mechanical examination.
  - If the manufacturer's facility is not equipped with adequate heat treatment or examination facilities then the manufacturer shall state the conditions under which these activities are subcontracted and shall provide the pertinent data for the operations involved.
  - Material supply information (including supplier details; confirmation that materials conform to purchase description; MSDS; reception, handling and storage of materials).
  - Records (e.g. calibration certificates) of inspection equipment used for measuring and testing.
  - Records of equipment used for metallographic examinations, mechanical tests, non-destructive tests, hydraulic and gaseous testing (where appropriate, this is to include details of the testing procedures used).
  - Training records of manufacturing and inspection personnel (personnel shall possess the requisite qualifications and/or demonstrate competence).
  - Current or future development which affects the supply must be reported in the following form:
    - summary description of development facilities;
    - research and development of grades;
    - publications.
- Quality Assurance (QA) documentation:
  - QA requirements are considered to be met through provision of a suitable quality management system (e.g. ISO 9001, ISO 13485, AS 9100) certified by a Certification Authority. However, this alone will not address the AM-specific requirements.

■ *Section 11* Organisational requirements

11.1 Leadership and commitment

The top management of the organisation shall demonstrate leadership and commitment with respect to the design, manufacture and inspection of the parts intended to be manufactured by AM by:

- Ensuring that the resources needed for the parts intended to be manufactured by AM are available.
- Ensuring that parts intended to be manufactured by AM achieve their intended outcomes.
- Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.
- Ensuring that any subcontracted operations are subject to adequate controls and inspection criteria in accordance with relevant quality requirements and these guidelines.

11.2 Resources

The organisation shall determine and provide the resources needed for the design, manufacturing and inspection and continual improvement of the parts intended to be manufactured by AM.

11.3 Competence

The organisation shall demonstrate the competence of the primary personnel roles (Designer, Programmer, Machine operator and Inspector) by:

- Ensuring that these personnel are competent on the basis of appropriate education, training or experience;
- Whenever necessary, taking actions to acquire the required competence and evaluate the effectiveness of the actions taken.

■ *Section 12* Intellectual property

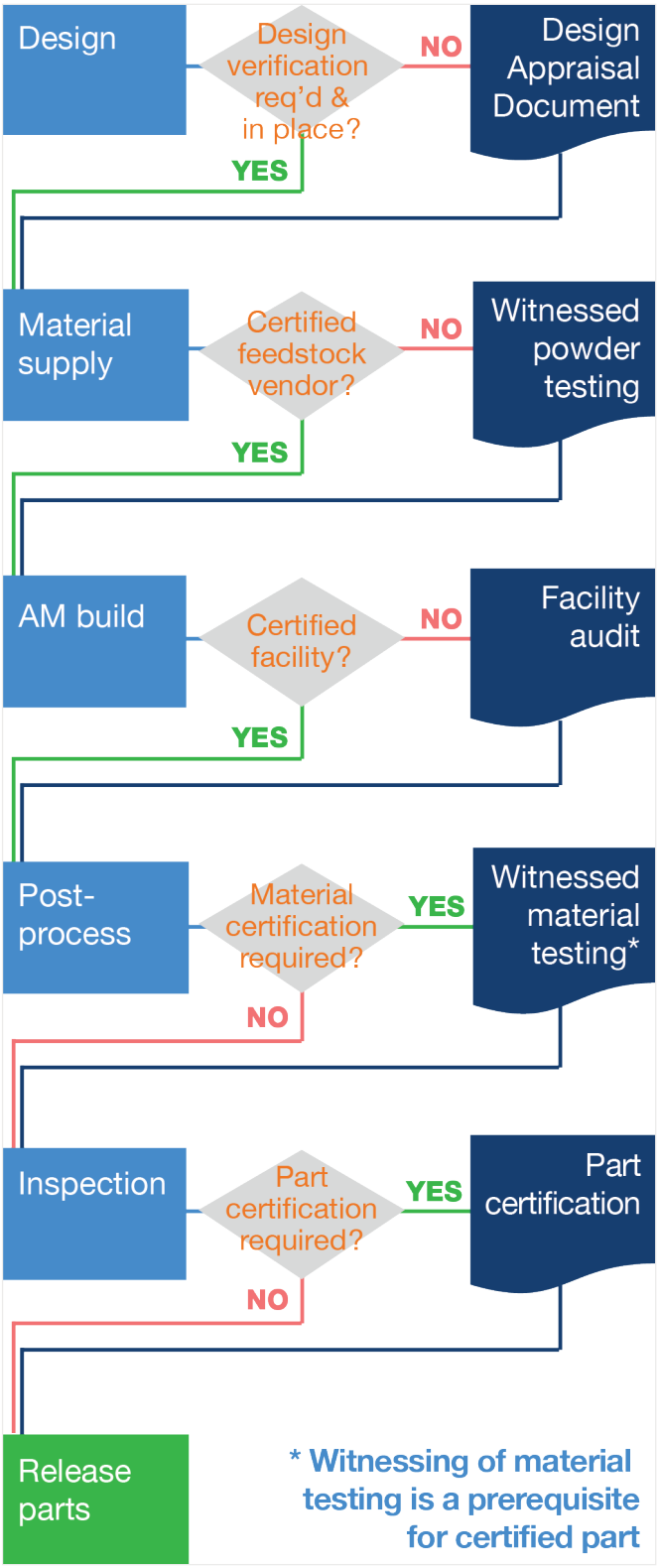
Designs used for AM are subject to current laws governing intellectual property (IP) and copyright. The IP of the design, along with the 3D CAD model and the manufacturing STL/AMF files, must be strictly controlled.

Designs, 3D CAD models and manufacturing files are protected by copyright. Any organisation utilising designs, 3D CAD models or manufacturing files shall retain evidence of the appropriate copyright licences.

Section 13
References

AS 9100	Aerospace Quality Management
HSG103	Safe Handling of Combustible Dusts: Precautions against Explosions.
IEC 60079-10-2	Explosive Atmospheres – Part 10-2: Classification of Areas – Explosive Dust Atmospheres.
ISO 3954	Powders for Powder Metallurgical Purposes Sampling
ISO 4490	Metallic Powders Determination of Flow Rate by Means of a Calibrated Funnel (Hall Flowmeter).
ISO 9001	Quality Management Systems
ISO 9276-6	Representation of Results of Particle Size Analysis Part 6: Descriptive and Quantitative Representation of Particle Shape and Morphology
ISO 13320	Particle Size Analysis Laser Diffraction Method.
ISO 13485	Medical Devices Quality management Systems
ISO 17296-2	Additive Manufacturing General Principles Part 2 Overview of Process Categories and Feedstock.
ISO 17296-3	Additive Manufacturing General Principles Part 3 Main Characteristic and Corresponding Test Methods.
ISO 17296-4	Additive Manufacturing General Principles Part 4 Overview of Data Processing
ISO/ASTM 52900:2015	Additive Manufacturing General Principles Terminology
ISO/IEC 14772 1:1997	Information Technology Computer Graphics and Image Processing The Virtual Reality Modelling Language Part 1: Functional Specification and Utf-8 Encoding
ISO/IEC 14772 2:2004	Information Technology Computer Graphics and Image Processing The Virtual Reality Modelling Language (VRML) Part 2: External Authoring Interface (EAI).
Lloyd's Register Materials and Qualification Procedures for Ships	Lloyd's Register Materials and Qualification Procedures for Ships Book L, Procedure 15-1, Approval Scheme for Firms Undertaking Thermal Spraying Processes.
NISTIR 8005	Applicability of Existing Materials Testing Standards for Additive Manufacturing Materials.

Appendix 1
Certification flowchart



■ *Appendix 2* Health and safety

This section provides information on the key hazards and risks associated with AM and the duties of the Additive Manufacturer to ensure protection of health and safety.

The typical health and safety risks associated with AM include the following:
- Dust fire and explosion.
- Exposure to hazardous substances.
- Hazardous atmospheres.
- Artificial optical radiation (AOR).
- Moving machinery.

A2.1 Dust, fire & explosion hazards

The fine metal dusts used in AM increase the risk of fire and explosion due to the creation of static electricity.

A suitable hazard identified and risk assessment must be carried out, and effective controls put in place to mitigate the risks from sources of electrostatic ignition.

Controls may include:
- Hazardous area classification.
- Intrinsically safe machinery, equipment and clothing.
- Fire prevention, suppression and containment systems.
- Dust explosion alarms.
- Explosion venting.

For further information, please refer to the applicable national/ international laws, regulations and guidance (e.g. for the UK, HSG 103 Safe Handling of Combustible Dusts: Precautions against Explosions).

A2.2 Exposure to hazardous substances

AM processes can include exposure to substances that are hazardous to health. These substances may include metal materials including nanoparticles that can cause serious illness if inhaled or absorbed through the skin.

In order to ensure adequate controls are in place, MSDS should be obtained for all hazardous substances, and an adequate hazard identification and risk assessment carried out.

Air monitoring should also be carried out as part of the hazard identification process, to ensure all potential airborne contaminants have been identified.

Safety controls may include:
- Containment systems.
- Exhaust ventilation systems.
- Personal protective equipment (PPE) (e.g. full body-suit and mask when working with powder particles < 20 µm).
- Respiratory protective equipment (RPE).

A2.3 Hazardous atmospheres

In AM, hazardous atmospheres can be caused as a result of dusts, fumes and gases released during AM processes. Hazardous atmospheres can also be caused by shielding gases (e.g. argon and helium) as they can cause oxygen displacement.

In order to ensure adequate controls are in place, MSDS should be obtained for all hazardous substances, and an adequate hazard identification and risk assessment carried out.

Safety controls may include:
- Ventilation systems.
- Gas alarm systems that can monitor and detect changes in oxygen levels and air pressure.
- Appropriate storage facilities for hazardous substances.
- Emergency plan in the event of an accidental release or spill.

A2.4 Artificial optical radiation

AOR includes light emitted from all artificial sources such as ultraviolet, infrared and laser beams.

Sources of optical radiation in AM include:
- The use of lasers to melt during manufacture.
- The use of melting arc during WAAM activities emits ultraviolet light.

Exposure to AOR can result in serious injury/illness including:
- Severe burns.
- Damaged eyes or loss of vision.
- Death.

In order to ensure appropriate controls are put in place to reduce the risk from AOR hazards, all hazards should be identified and a detailed assessment of risks carried out.

Controls may include:
- Safety screens.
- Remote viewing.
- Safety clamps and interlocking systems.
- PPE such as face shields.
- Restricting access and safety warnings.

All personnel working with sources of AOR should be fully trained and competent to do so.

A2.5 Moving machinery

Moving machinery and automated parts pose a safety risks to personnel including collision with mechanical parts and entrapment.

In order to ensure appropriate controls are put in place to reduce the risk from automated machinery hazards, all hazards should be identified and a detailed assessment of risks carried out.

Controls may include:

- Ensure all personnel working with machinery are trained and competent to do so.
- Run programmes from outside of the machinery workspace.
- Use of speed limiters.
- Use of interlocking devices, emergency shut off laser beams and emergency stop buttons.
- Exclusion zone markings and safety signage.

A2.6 Safety requirements for manufacturers

The following are a summary of the basic safety requirements for manufacturers using AM:

- Comply with all relevant national and international safety regulations for AM.
- Ensure an identification of hazards and assessment of risks has been carried out for all activities.
- Ensure adequate safety controls are in place for the protection of human life.
- Ensure appropriate training and competence for all personnel working in AM.
- Ensure an appropriate emergency response plan is in place to deal with potential injuries, illnesses and accidental releases of harmful substances.

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