AMERICAN MANUFACTURING COMPLIANCE AUTHORITY

3D PRINTING QUALITY STANDARD

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AMERICAN MANUFACTURING COMPLIANCE AUTHORITY (AMCA)
QUALITY STANDARDS FOR INDUSTRIAL 3D PRINTING (Additive Manufacturing)
Version 1.0

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1. Purpose and Scope

These Quality Standards establish baseline requirements for the design, production, verification, and documentation of parts manufactured using 3D printing (additive manufacturing) technologies within the United States. They apply to all organizations engaged in industrial, commercial, or regulated production using polymer, metal, composite, or hybrid additive processes.

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2. Definitions

- **Additive Manufacturing (AM):** A manufacturing process that builds parts layer-by-layer from digital models.
- **Build File:** The validated digital file used to generate machine instructions.
- **Critical Feature:** A feature whose dimensional accuracy, surface quality, or mechanical performance affects functionality or safety.
- **Lot:** A defined batch of printed parts produced under similar settings and environmental conditions.

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3. General Requirements

3.1 **Quality Management System (QMS)**
Organizations must maintain a documented QMS covering additive manufacturing operations, including risk analysis, material control, equipment qualification, and personnel training.

3.2 **Document Control**
All design files, machine settings, inspection records, and revision histories must be stored in secure, traceable systems.

3.3 **Personnel Competency**
Operators, technicians, and inspectors must receive documented training on equipment operation, safety, quality control, and material-specific considerations.

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4. Design and File Preparation

4.1 **Design Validation**
All parts must undergo design review to confirm manufacturability, mechanical requirements, thermal considerations, and support strategy.

4.2 **File Integrity**
The build file must be checked for:

- Mesh integrity (no holes or inverted normals)
- Correct orientation
- Proper wall thicknesses
- Support structure optimization

4.3 **Version Control**
All build files must have unique version numbers, with changes approved and documented before production.

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5. Materials Management

5.1 **Material Certification**
Raw materials (powders, filaments, resins, composites) must arrive with manufacturer certificates confirming composition, batch number, and expiration date.

5.2 **Storage Requirements**
Materials must be stored under conditions appropriate to their type, including humidity control, temperature stability, and contamination prevention.

5.3 **Material Reuse Policy**
Organizations must document:

- Maximum number of reuse cycles
- Mixing ratios of virgin and recycled material

- Testing required for reused powder (particle size, flow rate, contamination)

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6. Equipment Qualification

6.1 **Machine Calibration**
Printers must be calibrated at intervals specified by the manufacturer or internal QMS, covering:

- Laser/electron beam alignment (metal)
- Extruder temperature accuracy (FDM/FFF)
- Resin curing parameters (SLA/DLP)
- Platform leveling and repeatability

6.2 **Maintenance Logs**
Every machine must maintain a log of maintenance events, corrective actions, and replacement components.

6.3 **Software Validation**
Firmware and slicing software must be verified for correct function after updates or configuration changes.

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7. Production Requirements

7.1 **Build Environment Control**
Environmental variables (temperature, humidity, particle contamination, inert gas levels) must be monitored and recorded for metal and polymer systems.

7.2 **Build Setup Verification**
Operators must complete pre-build checklists confirming:

- Correct machine setup
- Material lot identification
- Build plate cleanliness
- Support structures and orientation matching approved file

7.3 **In-Process Monitoring**
For each build, the following must be recorded:

- Layer monitoring data (if available)
- Machine alarms or interruptions
- Material consumption
- Deviations from nominal process parameters

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8. Post-Processing Requirements

8.1 **Support Removal**
Supports must be removed using methods that do not compromise dimensional accuracy or mechanical integrity.

8.2 **Heat Treatment / Curing**
Parts requiring thermal processing (annealing, sintering, stress-relief) must follow validated time–temperature profiles.

8.3 **Surface Finishing**
Finishing processes (sanding, polishing, machining, bead blasting, coating) must be controlled and documented to avoid altering critical features.

8.4 **Cleaning**
Parts must be cleaned of loose powder, resin residue, or debris prior to inspection, using approved methods.

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9. Inspection and Testing

9.1 **Dimensional Inspection**
Critical dimensions must be verified using calibrated measurement tools such as:

- CMM
- Laser scanners
- Optical systems
- Micrometers and gauges

9.2 **Mechanical Testing**
When required, organizations must conduct:

- Tensile testing

- Hardness testing
- Fatigue testing
- Density or porosity evaluation

9.3 **Non-Destructive Testing (NDT)**
For high-risk applications, NDT methods such as CT scanning, ultrasonic testing, or dye-penetrant inspection must be used.

9.4 **Lot Acceptance**
Parts failing any critical test must result in lot quarantine, root-cause analysis, and corrective action.

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10. Traceability

10.1 **Identification Marking**
Each part must be labeled (physically or digitally) with a unique identifier linking it to its production record.

10.2 **Record Retention**
Organizations must retain production and inspection records for a minimum of 7 years or per applicable industry regulations.

10.3 **Build History**
Each identifier must link to:

- Machine used
- Material lot numbers
- Build parameters
- Post-processing steps
- Inspection results

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11. Nonconformance and Corrective Action

11.1 **Nonconformance Handling**
Any deviation from approved design, settings, or quality must be documented, evaluated, and dispositioned (rework, scrap, or acceptance with justification).

11.2 **Corrective and Preventive Actions (CAPA)**
Root-cause analysis must be performed for recurring issues, with actions tracked until verified as effective.

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12. Safety Requirements

12.1 **Material Safety**
Personnel must use protective equipment when handling powders, resins, or high-temperature components.

12.2 **Machine Safety**
Equipment must include interlocks, shielding, ventilation, and emergency shutoff devices.

12.3 **Environmental Safety**
Facilities must manage waste materials and emissions according to federal, state, and local regulations.

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13. Continuous Improvement

13.1 **Performance Review**
Organizations must review additive manufacturing process performance at least annually.

13.2 **Technology Updates**
New materials, machines, and processes must be validated before integration into production.

13.3 **Data Analytics**
Build data, machine metrics, and inspection outcomes should be analyzed to identify trends and opportunities for improvement.

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14. Compliance Statement

Organizations implementing these standards affirm their commitment to safe, reliable, and traceable additive manufacturing practices consistent with AMCA quality requirements.

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