INJECTION MOLDING QUALITY STANDARD

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AMERICAN MANUFACTURING COMPLIANCE AUTHORITY (AMCA)
QUALITY STANDARDS FOR INJECTION-MOLDING

1. Purpose and Scope

These standards, issued by the American Manufacturing Compliance Authority (AMCA), establish the minimum quality, safety, and process-control requirements for injection-molded components used in industrial, consumer, automotive, aerospace, medical, and general commercial applications.
They apply to all organizations engaged in design, tooling, production, testing, or validation of injection-molded plastic parts.

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2. Definitions

2.1 Injection Molding

A manufacturing process wherein molten thermoplastic or thermoset material is injected into a mold cavity to form a solidified part.

2.2 Critical-to-Quality (CTQ) Feature

Any dimension, property, or characteristic essential to part function, safety, or regulatory compliance.

2.3 Lot

A production quantity manufactured under uniform conditions from the same material batch.

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3. Material Standards

3.1 Material Certification

All resins must be purchased from approved suppliers and accompanied by Certificates of Analysis verifying:

- Melt flow index
- Moisture content
- Density
- Mechanical properties

- Compliance with relevant safety standards (e.g., flammability ratings, chemical restrictions)

3.2 Material Handling

- Hygroscopic materials shall be dried per manufacturer recommendations.
- Regrind usage shall not exceed 15% unless otherwise validated.
- Material storage areas must prevent contamination, moisture absorption, and degradation.

3.3 Material Traceability

Each lot of finished parts must be traceable to resin batch, production date, and machine run conditions.

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4. Tooling and Mold Requirements

4.1 Mold Design

Molds shall be designed to support consistent fill, balanced cooling, and dimensional stability. Designs must include:

- Adequate venting
- Wear-resistant components at high-friction surfaces
- Ejector systems that avoid part deformation
- Gate design compatible with material and product geometry

4.2 Mold Maintenance & Inspection

- Preventive maintenance intervals must be defined by mold class and production volume.
- Molds must be inspected for wear, contamination, flash causes, and alignment issues.
- Maintenance actions shall be documented and stored for audit review.

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5. Process Control Standards

5.1 Setup Verification

Before production, the following must be validated:

- Mold temperature
- Barrel temperature profile
- Injection pressure and speed
- Holding/packing pressure
- Cooling time
- Clamp force
- Screw speed and back pressure

5.2 Process Monitoring

During operation, machines must continuously monitor and record:

- Shot-to-shot consistency
- Cycle time
- Injection and hold pressures
- Material temperature
- Screw position and recovery time
  Alarms shall be configured for deviations beyond established control limits.

5.3 Process Validation

All production processes must undergo IQ (Installation Qualification), OQ (Operational Qualification), and PQ (Performance Qualification) where applicable. Validation data must show stable production with acceptable Cpk and Ppk values for CTQ dimensions.

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6. Dimensional and Visual Quality Requirements

6.1 Dimensional Conformance

- All dimensions must meet tolerances specified in the engineering drawing.
- CTQ features require 100% inspection or validated sampling plans.
- Measurement equipment must have adequate accuracy (GR&R ≤ 10% preferred).

6.2 Visual Standards

Parts shall be free from:

- Flash
- Short shots
- Burn marks
- Splay
- Sink marks (beyond allowed cosmetic tolerance)
- Weld line weakness (unless approved through mechanical testing)
- Contamination, discoloration, or foreign material

6.3 Surface Finish Requirements
Surface textures must conform to mold specifications. No unauthorized polishing or surface alteration is permitted.

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7. Mechanical and Functional Testing

7.1 Mechanical Testing
As applicable to product requirements:

- Tensile, flexural, or impact testing
- Hardness measurements
- Burst or pressure testing
  Results must meet or exceed engineering requirements.

7.2 Environmental Testing
For performance-critical applications, parts shall be validated for:

- Heat aging
- UV exposure
- Chemical resistance
- Humidity cycling
- Dimensional stability across temperature ranges

7.3 Fit and Assembly Testing
All mating parts must assemble without excessive force, deformation, or interference.

Functional performance shall match design intent.

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8. Nonconformance and Corrective Action

8.1 Identification and Segregation

Nonconforming parts must be immediately identified, segregated, and logged. Rework is only permitted under approved procedures.

8.2 Root Cause Analysis

All significant or repeated nonconformances require documented root-cause analysis using AMCA-approved methodologies (e.g., 8D, Ishikawa, 5-Whys).

8.3 Corrective and Preventive Action (CAPA)

Corrective actions shall include:

- Defined responsibilities
- Implementation deadlines
- Effectiveness verification
  Preventive actions shall address system-level improvements to avert recurrence.

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9. Documentation and Recordkeeping

9.1 Required Documentation

Manufacturers must retain the following:

- Material certifications
- Process setup sheets
- Maintenance logs
- Inspection and test results
- CAPA records
- Production traceability data
  Documents must be stored for a minimum of five years unless otherwise specified.

9.2 Revision Control

All production documents must carry revision numbers. Outdated documents must be removed from use immediately.

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10. Packaging and Shipment Requirements

10.1 Packaging Integrity

Packaging must prevent deformation, contamination, or damage during handling and transit.
Protective measures shall adhere to part sensitivity levels (e.g., ESD-safe packaging for electronics-related components).

10.2 Labeling

Each shipment must include:

- Part number and revision
- Lot number
- Quantity
- Production date
- Special handling instructions

10.3 Transportation Standards

Shipments must comply with applicable national and international transportation regulations. Shock, vibration, and temperature protections shall be used when required.

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11. Supplier Compliance

Suppliers must maintain a quality management system aligned with ISO 9001 or equivalent. AMCA reserves the right to audit facilities, review documentation, and suspend certification due to noncompliance.

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12. Continuous Improvement

Manufacturers are encouraged to apply continuous improvement methodologies such as Lean, Six Sigma, or statistical process control to minimize defects, reduce

variation, and enhance sustainability.

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