AMERICAN MANUFACTURING
COMPLIANCE AUTHORITY

Engineering & Design QUALITY STANDARD

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AMERICAN MANUFACTURING COMPLIANCE AUTHORITY (AMCA)
QUALITY STANDARDS FOR PRODUCT ENGINEERING & DESIGN

1. Purpose and Scope

These Quality Standards establish the minimum requirements for organizations providing *Product Engineering & Design Services under the oversight of the American Manufacturing Compliance Authority (AMCA)*. The standards apply to all phases of product development, including conceptual design, engineering analysis, prototyping, validation, documentation, and pre-production readiness. The intent is to ensure safety, reliability, regulatory compliance, and manufacturability while promoting innovation and operational excellence.

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2. Organizational Competence and Responsibilities

2.1 **Competence Requirements**
Organizations shall maintain qualified personnel with demonstrable expertise in engineering principles, design methodologies, materials science, manufacturing processes, and applicable regulatory requirements.
2.2 **Roles and Responsibilities**
Clear assignment of responsibilities must be documented for project ownership, engineering review, design approval, regulatory verification, and configuration management.
2.3 **Training and Continued Professional Development**
Personnel must receive periodic training on updated industry standards, digital design tools, risk-management practices, and emerging technologies relevant to their engineering domain.

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3. Customer Requirements and Project Planning

3.1 **Requirement Capture**
All customer requirements—functional, aesthetic, environmental, and regulatory—shall be documented, reviewed, and formally approved before engineering activities begin.
3.2 **Feasibility Assessment**
A feasibility review must evaluate technical viability, manufacturing constraints,

material availability, risk factors, and cost targets.

3.3 **Project Planning**

A project plan shall define the schedule, milestones, design reviews, deliverables, verification steps, and change-control processes.

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4. Design & Engineering Process Controls

4.1 **Design Methodology**

Engineering and design activities shall follow a systematic methodology such as systems engineering, stage-gate development, or other structured approaches approved by the organization.

4.2 **Design Inputs**

Inputs must be complete, measurable, traceable, and aligned with customer requirements and regulatory obligations.

4.3 **Design Outputs**

Outputs—including CAD models, drawings, analysis reports, materials specifications, and bill of materials—shall meet design input requirements and be suitable for manufacturing.

4.4 **Design Reviews**

Multi-disciplinary design reviews must occur at defined stages to assess technical adequacy, risks, manufacturability, and compliance.

4.5 **Design Validation & Verification**

Verification ensures the design meets specifications; validation ensures the product fulfills its intended use. Methods may include simulation, prototyping, testing, field trials, and third-party evaluations.

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5. Risk Management

5.1 **Risk Identification & Assessment**

Organizations must identify risks associated with safety, performance, usability, manufacturability, supply chain, and environmental factors.

5.2 **Risk Mitigation**

Mitigation strategies shall be implemented, reviewed, and documented, including design redundancies, safety factors, alternative materials, or updated processes.

5.3 **Regulatory Risk Compliance**

Products shall be assessed against all relevant national and international standards

for safety, environmental impact, and performance, including AMCA-mandated sector requirements.

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6. Engineering Analysis and Simulation

6.1 **Analysis Requirements**
Finite element analysis (FEA), computational fluid dynamics (CFD), tolerance analysis, thermal studies, and other relevant analyses must be performed to validate design integrity.
6.2 **Model Integrity**
Engineering models and simulations must use validated data, documented assumptions, and peer-reviewed methods.
6.3 **Documentation**
All analysis shall be recorded in reproducible formats, including input parameters, boundary conditions, results, conclusions, and recommendations.

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7. Prototyping and Testing

7.1 **Prototype Development**
Prototypes must be manufactured to specifications representing the intended final design, unless otherwise justified.
7.2 **Testing Protocols**
Organizations shall conduct functional, environmental, durability, safety, and regulatory tests as applicable.
7.3 **Test Traceability**
Test methods, equipment calibration records, results, deviations, and corrective actions must be fully documented.

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8. Materials, Components, and Manufacturing Readiness

8.1 **Material Specification**
All materials and components must meet defined engineering specifications and relevant compliance standards.
8.2 **Supplier Qualification**

Suppliers must be evaluated for quality, consistency, and regulatory compliance.

8.3 **Design for Manufacturing (DfM)**

Designs shall incorporate manufacturability considerations such as tooling capability, dimensional tolerances, assembly processes, cost efficiency, and scalability.

8.4 **Pre-Production Approval**

Before release to manufacturing, the design must undergo final engineering approval, configuration freeze, and documentation verification.

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9. Change Management

9.1 **Change Control Process**

Any modification to design, materials, components, or specifications must follow a formal change-control process.

9.2 **Impact Assessment**

Changes shall be reviewed for effects on functionality, safety, compliance, manufacturability, and cost.

9.3 **Customer Notification**

Customer approval is required for changes that affect fit, form, function, reliability, or regulatory compliance.

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10. Documentation and Record-Keeping

10.1 **Document Control**

All engineering documents must be version-controlled, secure, accessible, and maintained in accordance with AMCA documentation requirements.

10.2 **Retention Requirements**

Records must be retained for a minimum of 10 years or as mandated by applicable regulations.

10.3 **Confidentiality**

Organizations shall implement safeguards to protect customer intellectual property, proprietary data, and design files.

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11. Quality Assurance and Internal Audits

11.1 **QA Oversight**
A dedicated quality assurance function shall monitor compliance with AMCA standards and internal procedures.
11.2 **Internal Audits**
Audits must be conducted at least annually to evaluate the effectiveness of engineering controls, documentation accuracy, risk management, and customer satisfaction.
11.3 **Corrective and Preventive Actions (CAPA)**
Non-conformities must be documented and resolved through defined CAPA processes that address root causes and long-term prevention.

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12. Continuous Improvement

12.1 **Process Optimization**
Organizations shall maintain programs promoting continuous improvement in engineering efficiency, design quality, cost control, and innovation.
12.2 **Performance Metrics**
Key performance indicators may include defect rates, design cycle times, customer satisfaction scores, and audit findings.
12.3 **Technology Advancement**
Adoption of new tools—including digital twins, AI-assisted design systems, and advanced simulation technologies—is encouraged where beneficial and validated.

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13. Ethics and Regulatory Compliance

13.1 **Ethical Engineering Practices**
All engineering decisions must prioritize safety, environmental stewardship, and integrity.
13.2 **Regulatory Compliance**
Organizations shall comply with all applicable national and international regulations governing product safety, environmental impact, labor standards, and data security.
13.3 **Transparency**
Accurate reporting of engineering performance, failures, and risks is mandatory.

14. Certification and Compliance Verification

14.1 **AMCA Certification**
Organizations may apply for AMCA Product Engineering & Design Certification, requiring full compliance with this standard.
14.2 **Surveillance Audits**
AMCA may conduct periodic surveillance audits to ensure continuing compliance.
14.3 **Non-Compliance**
Major non-conformities may result in corrective action mandates, suspension, or revocation of certification.

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