

EU AI Act

Article 17

Quality Management --- System

Article 17(1) requires providers of high-risk AI systems to put a quality management system in place that ensures compliance with this Regulation. That system shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions.

**13 Requirements
for the QMS of high-risk AI**

Requirements 1–5

01 **Regulatory Compliance Strategy**

A strategy for regulatory compliance, including conformity with conformity assessment procedures and management of changes to the high-risk AI system.

02 **Design Control and Verification**

Techniques, procedures and systematic actions for design, design control and design verification of the high-risk AI system.

03 **Development and Quality Assurance**

Techniques, procedures and systematic actions for development, quality control and quality assurance of the high-risk AI system.

04 **Testing and Validation**

Procedures and systematic actions for testing, verification and validation of the high-risk AI system, including pre- and post-market activities.

05 **Technical Specifications**

Data and data governance, including data collection, analysis, labelling, storage, filtration, mining, aggregation, retention and any other operation regarding the data.

Requirements 6–9

06

Data Management

The risk management system referred to in Article 9.

07

Risk Management

The setting-up, implementation and maintenance of a post-market monitoring system, in accordance with Article 72.

08

Post-Market Monitoring

Procedures related to the reporting of a serious incident in accordance with Article 73.

09

Incident Reporting

Communication with national competent authorities, other relevant authorities, including those providing or supporting access to data, notified bodies, other operators, customers or other interested parties.

Requirements 10–13

10 Stakeholder Communication

Systems and procedures for record-keeping of all relevant documentation and information.

11 Record-Keeping

Resource management, including security-of-supply related measures.

12 Resource Management

An accountability framework setting out the responsibilities of the management and other staff with regard to all the aspects listed in this paragraph.

13 Accountability Framework

Clear assignment of responsibilities and accountabilities across the organisation.

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