

ISO/IEC 9003:2004-02 (E)

Software engineering - Guidelines for the application of ISO 9001:2000 to computer software

| Contents | | Page |
|-----------------|--|-------------|
| 1 | Scope | 1 |
| 1.1 | General | 1 |
| 1.2 | Application | 1 |
| 2 | Normative references | 2 |
| 3 | Terms and definitions | 2 |
| 4 | Quality management system | 5 |
| 4.1 | General requirements | 5 |
| 4.2 | Documentation requirements | 6 |
| 4.2.1 | General | 6 |
| 4.2.2 | Quality manual | 6 |
| 4.2.3 | Control of documents | 7 |
| 4.2.4 | Control of records | 7 |
| 5 | Management responsibility | 8 |
| 5.1 | Management commitment | 8 |
| 5.2 | Customer focus | 8 |
| 5.3 | Quality policy | 9 |
| 5.4 | Planning | 9 |
| 5.4.1 | Quality objectives | 9 |
| 5.4.2 | Quality management system planning | 9 |
| 5.5 | Responsibility, authority and communication | 10 |
| 5.5.1 | Responsibility and authority | 10 |
| 5.5.2 | Management representative | 10 |
| 5.5.3 | Internal communication | 11 |
| 5.6 | Management review | 11 |
| 5.6.1 | General | 11 |
| 5.6.2 | Review input | 11 |
| 5.6.3 | Review output | 12 |
| 6 | Resource management | 12 |
| 6.1 | Provision of resources | 12 |
| 6.2 | Human resources | 12 |
| 6.2.1 | General | 12 |
| 6.2.2 | Competence, awareness and training | 13 |
| 6.3 | Infrastructure | 13 |
| 6.4 | Work environment | 14 |
| 7 | Product realization | 14 |
| 7.1 | Planning of product realization | 14 |
| 7.1.1 | Software life cycle | 15 |
| 7.1.2 | Quality planning | 15 |
| 7.2 | Customer-related processes | 16 |
| 7.2.1 | Determination of requirements related to the product | 16 |
| 7.2.2 | Review of requirements related to the product | 18 |
| 7.2.3 | Customer communication | 20 |
| 7.3 | Design and development | 21 |
| 7.3.1 | Design and development planning | 21 |
| 7.3.2 | Design and development inputs | 23 |

| | | |
|--|--|-----------|
| 7.3.3 | Design and development outputs | 24 |
| 7.3.4 | Design and development review | 25 |
| 7.3.5 | Design and development verification | 26 |
| 7.3.6 | Design and development validation | 26 |
| 7.3.7 | Control of design and development changes | 28 |
| 7.4 | Purchasing | 28 |
| 7.4.1 | Purchasing process | 28 |
| 7.4.2 | Purchasing information | 30 |
| 7.4.3 | Verification of purchased product | 30 |
| 7.5 | Production and service provision | 31 |
| 7.5.1 | Control of production and service provision | 31 |
| 7.5.2 | Validation of processes for production and service provision | 34 |
| 7.5.3 | Identification and traceability | 34 |
| 7.5.4 | Customer property | 35 |
| 7.5.5 | Preservation of product | 36 |
| 7.6 | Control of monitoring and measuring devices | 37 |
| 8 | Measurement, analysis and improvement | 38 |
| 8.1 | General | 38 |
| 8.2 | Monitoring and measurement | 38 |
| 8.2.1 | Customer satisfaction | 38 |
| 8.2.2 | Internal audit | 39 |
| 8.2.3 | Monitoring and measurement of processes | 40 |
| 8.2.4 | Monitoring and measurement of product | 40 |
| 8.3 | Control of nonconforming product | 41 |
| 8.4 | Analysis of data | 42 |
| 8.5 | Improvement | 42 |
| 8.5.1 | Continual improvement | 42 |
| 8.5.2 | Corrective action | 43 |
| 8.5.3 | Preventive action | 43 |
| Annex A (informative) Additional guidance in the implementation of ISO 9001:2000 available in | | |
| | Bibliography | 53 |