

Annex 1: Comparison of CLSI Quality Management System Model to ISO 9001 and ISO 15189*

| Quality Management System Model | ISO 9001:2000 | ISO 15189:2007 |
|------------------------------------|---|---|
| Organization | 4.1 _General requirements 5.1 _Management commitment 5.3 _Quality policy 5.4 _Planning 5.5 _Responsibility, authority, communication 5.6 _Management review 6.1 _Provision of resources | 4.1 _Organization and management 4.2 _Quality management system 4.15 _Management review Annex C.1 _General ethics Annex C.10 _Financial arrangements |
| Personnel | 6.2 _Human resources | 5.1 _Personnel |
| Equipment | 7.6 _Control of measuring and monitoring devices | 5.3 _Laboratory equipment Annex B.1 _General Annex B.7 _Hardware and software Annex B.8 _System maintenance |
| Purchasing and Inventory | 7.4 _Purchasing | 4.4 _Review of contracts 4.5 _Examination by referral laboratories 4.6 _External services and supplies |
| Process Control | 7.1 _Planning of product realization 7.2 _Customer-related processes 7.3 _Design and development 7.5 _Production and service provision | 5.4 _Pre-examination procedures 5.5 _Examination procedures 5.6 _Assuring the quality of examination procedures 5.7 _Post-examination process 5.8 _Reporting of results Annex C.5 _Examination Annex C.6 _Reporting results |
| Documents and Records | 4.2 _Documentation requirements | 4.3 _Document control 4.13 _Quality and technical records Annex C.7 _Storage/retention of medical records |
| Information Management | | Annex B.4 _System security Annex B.5 _Data entry and reports Annex C.3 _Information Annex C.4 _Consent Annex C.8 _Access to laboratory records Annex C.9 _Other purposes |
| Occurrence Management | 8.3 _Control of nonconforming product | 4.8 _Resolution of complaints 4.9 _Identification and control of nonconformities 4.10 _Corrective action |
| Assessments: External and Internal | 8.1 _General 8.2 _Monitoring and measurement 8.4 _Analysis of data | 4.1 _Preventive action 4.14 _Internal audits |
| Process Improvement | 8.5 _Improvement | 4.12 _Continual improvement |
| Customer Service | 5.2 _Customer focus | 4.7 _Advisory services Annex C.2 _General principles |
| Facilities and Safety | 6.3 _Infrastructure 6.4 _Work environment | 5.2 _Accommodation and environmental conditions Annex B.2 _Environment |

- ***Table source:** CLSI/NCCLS. *Application of a Quality Management System Model for Laboratory Services; Approved Guideline—Third Edition.* CLSI/NCCLS document GP26-A3. Wayne, PA: NCCLS; 2004.