

## NCCLS / ISO Cross-Reference Table

NCCLS Model Quality System <sup>1</sup>	ISO 9001:2000 <sup>2</sup>	ISO/IEC DIS 17025 <sup>3</sup>	ISO 15189 <sup>4</sup>
Quality System Essentials	Clauses	Clauses	Clauses
Organization	4.1 General 5.1 Management commitment 5.3 Quality policy 5.4 Planning 5.5 Responsibility, authority, and communication 5.6 Management review 6.1 Provision of resources	4.1 Organization and quality management 4.2 Quality System 4.4 Review of requests, tenders and contracts 4.5 Subcontracting of tests and calibrations 4.14 Management reviews	4.1 Organization and management 4.2 Quality management system
Personnel	6.2 Human resources	5.2 Personnel	5.1 Personnel
Equipment	7.6 Control of measuring and monitoring devices	5.5 Equipment 5.6 Measurement of traceability	5.3 Laboratory equipment
Purchasing and Inventory	7.4 Purchasing	4.6 Purchasing services and supplies	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	5.3 Accommodation and environmental conditions 5.4 Test and calibration methods 5.7 Sampling 5.8 Handling and transportation of test and calibration items 5.9 Assuring the quality of test and calibration results 5.10 Reporting the results	4.4 Referral of examinations to other laboratories 5.2 Accommodations and environmental conditions 5.4 Pre-examination procedures 5.5 Examination procedures 5.6 Assuring the quality of examination procedures 5.7 Post-examination procedures 5.8 Reporting results
Documents and Records	4.2 Documentation requirements	4.3 Document control 4.12 Control of records	4.3 Document control 4.13 Quality and technical records

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Quality System Essentials	Clauses	Clauses	Clauses
Information Management	8.4 Analysis of data	5.4.7 Control of data	4.2.4 Quality manual (Annex B)
Occurrence Management	8.3 Control of nonconforming product	4.9 Control of nonconforming testing and/or calibration work	4.9 Identification and control of nonconformities
Assessments	8.1 General 8.2 Monitoring and measurement	4.13 Internal audits	4.14 Internal audits
Process Improvement	8.5 Improvement	4.10 Corrective action 4.11 Preventive action	4.10 Corrective action 4.11 Preventive action
Customer Service and Satisfaction	5.2 Customer focus	4.7 Service to the client 4.8 Complaints	4.7 Advisory services 4.8 Resolution of complaints
Facilities and Safety	6.3 Infrastructure 6.4 Work environment	5.3 Accommodation & environmental conditions	5.2 Accommodation and environmental conditions

- 1 – NCCLS GP26-A2. *Application of a Quality System Model for Laboratory Services; Approved Guideline – Second Edition*
- 2 - ISO 9001:2000. *Quality management systems – Requirements.*
- 3 – ISO/IEC 17025.1999. *General requirements for the competence of testing and calibration laboratories.*
- 4 – ISO 15189:2002. *Medical laboratories – Particular requirements for quality and competence.*