

## Comparison: CLSI QMS Model to ISO 15189 and CLIA Regulations

CLSI QMS	ISO 15189	CLIA
QSE	Clauses	Sections
Organization	4.1 Organization and Management 4.2 Quality management system 4.15 Management review	§ 493.1200 – § 493.1299 Subpart K – Quality System for Non-Waived Testing
Personnel	5.1 Personnel	§ 493.1351 - § 493.1495 Subpart M – Personnel for Non-Waived Testing
Equipment	5.3 Laboratory Equipment	§ 493.1252 - § 493.1255 Equipment, performance verification, maintenance and function checks, calibration
Purchasing & Inventory	4.4 Contract review 4.5 Referral Laboratories 4.6 External Services and Supplies	§ 493.1242(8)(c) Specimen referral § 493.1252 Test systems, equipment, instruments, reagents, materials, and supplies
Process control	5.4 Pre-examination procedures 5.5 Examination procedures 5.6 Assuring quality – examination 5.7 Post-examination procedures	§ 493.1240 - § 493.1249 Pre-analytic systems § 493.1250 - § 493.1289 Analytic Systems § 493.1290 - § 493.1299 Post-analytic systems
Documents and records	4.3 Document Control 4.13 Quality and Technical Records	§ 493.1101(e) Standard: Facilities 493.1105 Standard: Retention Requirements
Information management	5.8 Reporting of results Annex B: LIS Annex C: Ethics	§ 493.1290 - § 493.1291 Post-analytic Systems
Occurrence management	4.8 Resolution of complaints 4.9 Identification and control of nonconformities 4.10 Corrective action	§ 493.1299 Post-analytic systems quality assessment § 493.1256 - § 493.1282 Control procedures
Assessments: Internal & External	4.11 Preventive action 4.14 Internal audits 5.6.4 External quality assessment	§ 493.1250 - § 493.1255 Analytic Systems § 493.801- § 493.865 Participation in Proficiency Testing Subpart Q - Inspection
Process improvement	4.12 Continual improvement	§ 493.1200, § 493.1239, § 493.1249, § 493.1289, § 493.1299 Quality Systems assessments
Customer service	4.7 Advisory services 4.8 Resolution of complaints Annex C: ethics	§ 493.1407, § 493.1419 Consultation § 493.1233 Complaint investigation § 493.1234 Communication
Facilities and Safety	4.6 External services and supplies 5.2 Accommodation and environmental conditions 5.3 Laboratory equipment	§ 493.1100 - § 493.1101 Facility Administration for Non-waived Testing § 493.1252 Standard: Test systems, equipment, etc.,