



# ISO 15189 — Integration of Requirements in 2012 and 2022 Versions

## 2012 Version

### 4.0 Management Requirements

- 4.1 Organization and Management Responsibility
- 4.2 Quality Management System
- 4.3 Document Control
- 4.4 Service Agreements
- 4.5 Examination by Referral Laboratories
- 4.6 External Services and Supplies
- 4.7 Advisory Services
- 4.8 Resolution of Complaints
- 4.9 Identification and Control of Nonconformities
- 4.10 Corrective Action
- 4.11 Preventive Action
- 4.12 Continual Improvement
- 4.13 Control of Records
- 4.14 Evaluation and Audits
- 4.15 Management Review

### 5.0 Technical Requirements

- 5.1 Personnel
- 5.2 Accommodation and Environmental Conditions
- 5.3 Laboratory Equipment, Reagents, and Consumables
- 5.4 Pre-Examination / Preanalytical Processes
- 5.5 & 5.6 Examination / Analytical Processes
- 5.7, 5.8 & 5.9 Post-Examination / Reporting of Results
- 5.10 Laboratory Information Management

## 2022 Version

### 4.0 General requirements

- 4.1 Impartiality
- 4.2 Confidentiality
- 4.3 Requirements regarding patients

### 5.0 Structural and governance requirements

- 5.1 Legal entity
- 5.2 Laboratory director
- 5.3 Laboratory activities
- 5.4 Structure and authority
- 5.5 Objectives and policies
- 5.6 Risk Management

### 6.0 Resource requirements

- 6.1 General
- 6.2 Personnel
- 6.3 Facilities and environmental conditions
- 6.4 Equipment
- 6.5 Equipment calibration and metrological traceability
- 6.6 Reagents and consumables
- 6.7 Service agreements
- 6.8 Externally provided products and services

### 7.0 Process requirements

- 7.1 General
- 7.2 Pre-examination processes
- 7.3 Examination Process
- 7.4 & 7.4.1 Post-examination processes; Reporting of results
- 7.5 Nonconforming work
- 7.6 Control of data and information management
- 7.7 Complaints
- 7.8 Continuity and emergency preparedness planning

### 8.0 Management system requirements

- 8.1 General requirements
- 8.2 Management system documentation
- 8.3 Control of management system documents
- 8.4 Control of records
- 8.5 Actions to address risks and opportunities for improvement
- 8.6 Improvement
- 8.7 Nonconformities and corrective actions
- 8.8 Evaluations
- 8.9 Management reviews

