ISO 15189 for Medical Laboratories

Quality and competence requirements for clinical analysis laboratories

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CHAPTER 1

What is — ISO 15189

ISO 15189 is the international standard specifying quality and competence requirements for medical laboratories. It is applicable to all disciplines: clinical chemistry, serology, microbiology, haematology and coagulation, immunology, immunohaematology, cytology, molecular biology and histopathology.

Why a specific standard

Medical laboratories have needs that ISO 9001 cannot adequately address. The quality of a laboratory result depends on highly specific technical factors: analytical staff competence, method validation, internal quality control, participation in external quality assessment programmes, critical value management, and accurate, timely reporting.

Scope of application

The standard applies to clinical analysis laboratories regardless of size, legal structure (public or private) or number of disciplines covered. Accreditation is granted by national bodies — in Italy by Accredia — and guarantees international recognition of results through ILAC/MRA agreements.

CHAPTER 2

ISO 15189 — vs ISO 9001

The pizza metaphor

To explain the relationship between the two standards, we use a culinary metaphor: ISO 9001 is the pizza base — the organisational structure, management processes, documentation system, auditing, management review. ISO 15189 is the toppings — the specific technical requirements that make the laboratory competent and its results reliable.

Without the base, the toppings don't hold together. But without the toppings, the base is just bread. A laboratory certified to ISO 9001 has demonstrated structured organisational processes. A laboratory accredited to ISO 15189 has also demonstrated that its results are reliable, accurate and reproducible.

What ISO 15189 adds

- Specific requirements for analytical staff competence (not just generic training)
- Validation and verification of analytical methods before clinical use
- Internal quality control (IQC) on every analytical run
- Mandatory participation in external quality assessment programmes (EQA/PT)
- Critical value management with urgent communication protocols
- Specific requirements for pre-examination and post-examination phases, where the majority of errors occur
- Measurement uncertainty estimation for quantitative methods

CHAPTER 3

Management requirements — (Chapter 4)

Chapter 4 of ISO 15189 defines the laboratory's management requirements. They are the "pizza base": the organisational structure and governance processes without which the technical requirements cannot be effectively implemented.

- Organisation: legal identity, independence of professional judgement, conflict of interest, confidentiality
- Quality management system: policy, objectives, planning, responsibilities
- Document control: approval, distribution, revision, archiving of all quality system documents
- Contracts and agreements: agreements with requestors, service specifications, complaint management
- Referral laboratories: selection criteria, performance monitoring, documented agreements
- External services and supplies: evaluation and qualification of critical suppliers
- Advisory and interpretation services: support to clinicians in test selection and result interpretation

- Complaint management: receipt, recording, analysis, response, corrective actions
- Non-conformities and corrective actions: identification, recording, cause analysis, effective actions
- Preventive actions: identification of potential risks and proactive mitigation measures
- Continuous improvement: structured programme with measurable indicators and objectives
- Records: retention of all technical and management records for the specified period
- Internal audits: planned programme covering all laboratory processes
- Management review: periodic analysis of quality data and strategic decisions

CHAPTER 4

Technical requirements — (Chapter 5)

Chapter 5 of ISO 15189 defines the technical requirements. It is the "toppings" that make the laboratory competent.

Personnel

The laboratory director has over 15 specific duties defined by the standard, from technical supervision to resource management. Every operator must have documented, assessed and maintained competencies. Competency assessment is not a one-off event: it is a continuous process with defined methods (direct observation, QC sample analysis, proficiency testing).

Pre-examination phase

The pre-examination phase encompasses everything that occurs before analysis: from the clinician's request to sample preparation for analysis. This is the phase where the majority of errors occur: incomplete requests, incorrect identification, inadequate collection, non-compliant transport, acceptance without verification.

Examination phase

The actual analysis: method selection and validation, calibration, internal quality control on every analytical run, participation in EQA/PT programmes, critical value management with urgent communication protocols to the clinician.

Post-examination phase

From result to clinician communication: technical and clinical report validation, turnaround times (TAT) monitoring, interpretive advisory, sample retention and disposal management.

CHAPTER 5

Laboratory — macro-processes

An ISO 15189-accredited medical laboratory manages approximately 25 macro-processes, organised into governance, operational and support processes.

Governance processes

- Quality management and continuous improvement
- Document and record management
- Internal audits and management review
- Non-conformity, corrective and preventive action management
- Complaint management and customer satisfaction

Operational processes

- Request management and sample acceptance
- Pre-analytical phase: collection, identification, transport
- Analytical phase: execution, calibration, quality control
- Post-analytical phase: validation, reporting, critical value communication
- EQA/PT programme management

Support processes

- Personnel management: training, competencies, assessment
- Equipment management: qualification, calibration, maintenance

- Reagent, calibrator and control material management
- Environment management: environmental conditions, safety, access
- Emergency management: continuity plan, emergency procedures

The records to be maintained are extensive: request forms, results, instrument printouts, calibration data, IQC data, EQA results, incident records, training records and much more.

CHAPTER 6

The pathway — with ICMED

ICMED accompanies medical laboratories through the ISO 15189 accreditation pathway with a structured and pragmatic approach, from the initial assessment to the Accredia accreditation audit.

- Detailed gap analysis against all ISO 15189 requirements, with section-by-section report and prioritised action plan
- Documentation system development: quality manual, SOPs for every process, work instructions, forms, records
- ECM training for staff on technical requirements (method validation, IQC, EQA) and management requirements (audit, NC, CAPA)
- Support in analytical method validation and verification, including measurement uncertainty estimation
- Preparation for the Accredia accreditation audit with mock audits and simulations
- IAAPP: integrated quality system management for the laboratory — documents, NC, CAPA, audits, indicators, training, equipment

LEARN MORE

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info@icmed.net

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ICMED S.r.l. — Via Fratelli Casiraghi 34, 20099 Sesto San Giovanni (MI)
P.IVA 10054340962 — REA MI-2501287