

# EQAsia

## General Introduction to ISO Accreditation



The Fleming Fund  
Regional Grants



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# House keeping rules



Please turn off your microphones – this will help with bandwidth and maximize audibility.



Do frequently use the chat function to share your views, comments and challenges. Keep the chat constructive, respectful and on topic!



If you would like to ask questions, please type them in the chat box



Please note that we will record the session to maintain a record of the questions asked and to distribute it to the laboratory team for future reference.



**International  
Vaccine  
Institute**

**ISO  
ACCREDITATION**



## **General Introduction to ISO Accreditation**

*(Basic requirements of ISO 15189, ISO 17025, ISO 17043)*

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# Blue print of presentation





World War II munitions quality issues directly spurred the laboratory accreditation as early as 1940's

Can you guess When is the necessity for accreditation originated ?

# Which recognition should we pursue?



## Accreditation

Focuses on technical competence and laboratory proficiency, suitable for technical services.

ISO :15189 & ISO 17025



## Certification

Emphasizes management system implementation and compliance, ideal for management processes.

ISO : 9001



# Introduction to ISO Accreditation

ISO accreditation is a **third-party verification that an organization meets the requirements of a specific ISO standard.**

**ISO Accreditation: The Global Benchmark for Quality and Trust.**

# ISO - International Organization of Standards

- ISO is not an acronym, It's a Greek word *isos* meaning **Equal , Same , Uniform**
  - ISO was created after World War II to promote **international harmony** through **globally accepted standards** that ensure quality, safety, and reliability.
  - **23 February 1947**: ISO was officially founded in **Geneva, Switzerland**.
  - Members from **173 Countries & developed over 24,000 international standards**  
This covers the domains such as technology, health, laboratories, environment, safety, governance, and services
- The member countries are represented as **full members, correspondent members, and subscriber members** depending on their **level of participation and development status**.

## Some Notable ISO Standards

Standard	Focus Area
ISO 9001	Quality management systems <a href="#">iso+1</a>
ISO 14001	Environmental management systems <a href="#">iso+1</a>
ISO 45001	Occupational health and safety <a href="#">iso+1</a>
ISO/IEC 27001	Information security management <a href="#">iso+1</a>
ISO 22000	Food safety management <a href="#">ansi+1</a>
ISO 13485	Medical devices quality management
ISO 21001	Educational organizations
ISO 14644	Cleanrooms and controlled environments
ISO 37301	Compliance management systems <a href="#">ansi</a>

## CRITERIA FOR CHOOSING THE APPROPRIATE ISO STANDARDS WITH IN YOUR COUNTRY

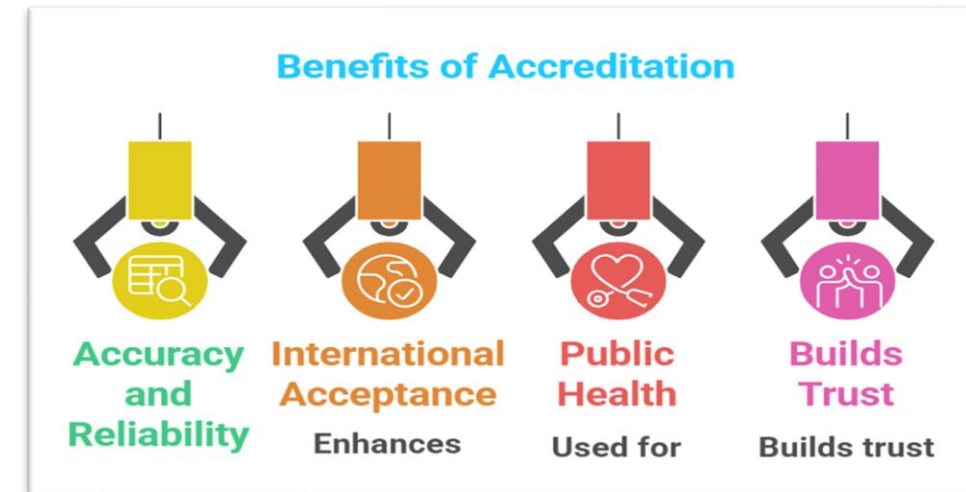
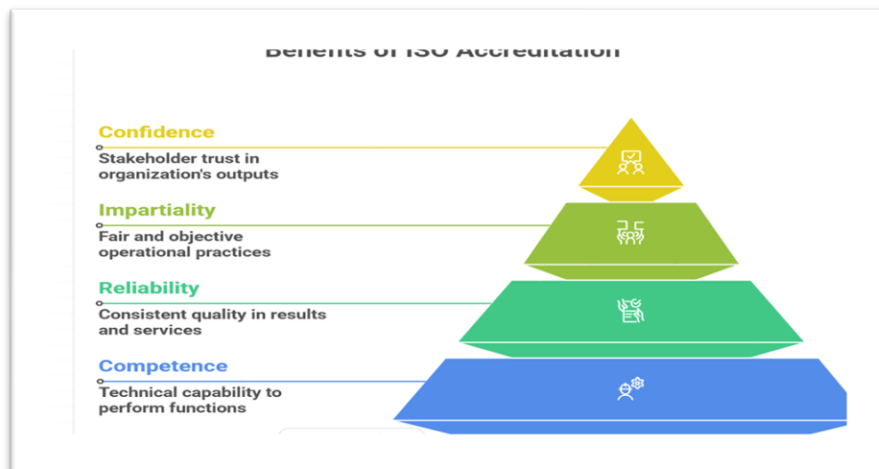
- Define the National Mandate of the Laboratory such as Disease surveillance, Confirmatory testing, Reference material provision, Method validation, Proficiency testing coordination & Regulatory decision-making decides type of ISO standards  
*(This mandate determines the primary ISO standard)*
- Identify the Nature of Laboratory Activities . If your lab activity confine to Medical /Clinical testing of Patient diagnostics/ Public Health - ISO 15189
- Testing and Calibration of Food environment, drugs, materials, Veterinary sample - ISO 17025
- Proficiency testing /Comparison of laboratories - ISO 17043

**AMR/ One health/ Zoonotic disease diagnosis in Human samples- ISO 15189**

**Same samples detected from Environmental, animal, food - ISO 17025**

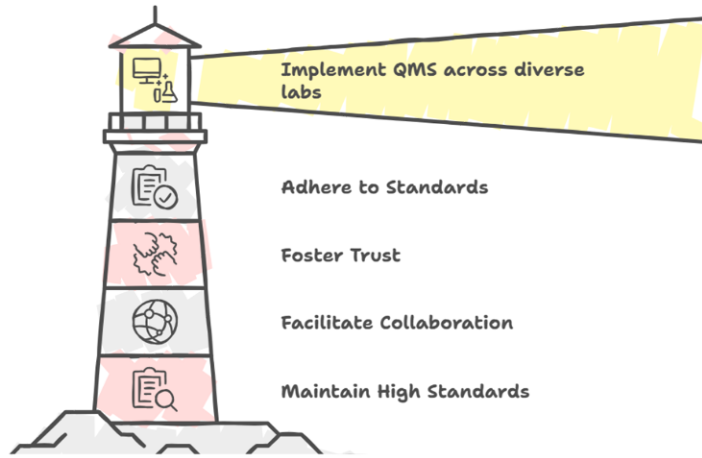
## BENEFITS OF ACCREDITATION

- Ensures **technical competence** and **accurate, reliable test results**
- Provides **international recognition** and global acceptance of lab data
- Enhances **Market competitive advantage** and **credibility & trust** among public health authorities & regulators
- Strengthens **disease surveillance** and **effective outbreak response**
- Ensures **standardization, quality assurance, and consistency** in laboratory practices
- Promotes **continuous improvement culture** and **regulatory compliance**



# NEED FOR ISO ACCREDITATION FOR NATIONAL REFERENCE LABORATORIES

Need of ISO Accreditation for National Reference Labs



- For harmonized quality and technical competence across diverse laboratory systems
- Enables **cross-border recognition** and acceptance of laboratory results for surveillance and trade
- Strengthens **regional disease surveillance**, early warning, and coordinated outbreak response (e.g., pandemics, AMR, zoonoses)
- Supports **data comparability and sharing** for regional and global reporting obligations
- Enhances **biosafety, biosecurity, and risk management** in high-threat and emerging disease contexts
- Aligns national reference laboratories with **WHO, IHR (2005), and global health security frameworks**
- Facilitates **capacity building, workforce development, and continuous quality improvement**

## LAB READINESS FOR ACCREDITATION – KEY POINTS

- Establish a **documented Quality Management System (QMS)** aligned with ISO standards
- Ensure **trained and competent staff** with defined roles and responsibilities
- Implement **validated methods, SOPs, and equipment calibration**
- Maintain **internal quality control** and participate in **proficiency testing**
- Ensure **biosafety, biosecurity, and proper record management**
- Conduct **internal audits and management reviews** for continual improvement

### One-line takeaway:

👉 *Accreditation readiness means the lab is technically competent, well-documented, and consistently delivering reliable results.*

## HIGH-LEVEL STRUCTURE (HLS ) OF ISO ORGANIZATION

- 1. Scope-** **Define the purpose and activities proposed**
- 2. Normative References-** Lists other standards & documents that are essential
- 3. Terms and Definitions** - meanings of key terms used in documents & manual
- 4. General Requirements** - impartiality, confidentiality, and patient focus
- 5. Structural Requirements-** labs legal status, organization, leadership & responsi
- 6. Resource Requirements-** personnel, facilities, equipment, reagents etc
- 7. Process Requirements-** controls over pre-examination, examination, and post-examination processes to ensure accurate and reliable results
- 8. Management System Requirements-** quality management system needed to control processes, manage risks, and drive continual improvement.

# **PRACTICAL IMPLEMENTATION FOR NATIONAL REFERENCE LABS**

## **Step-by-Step Roadmap to Accreditation**

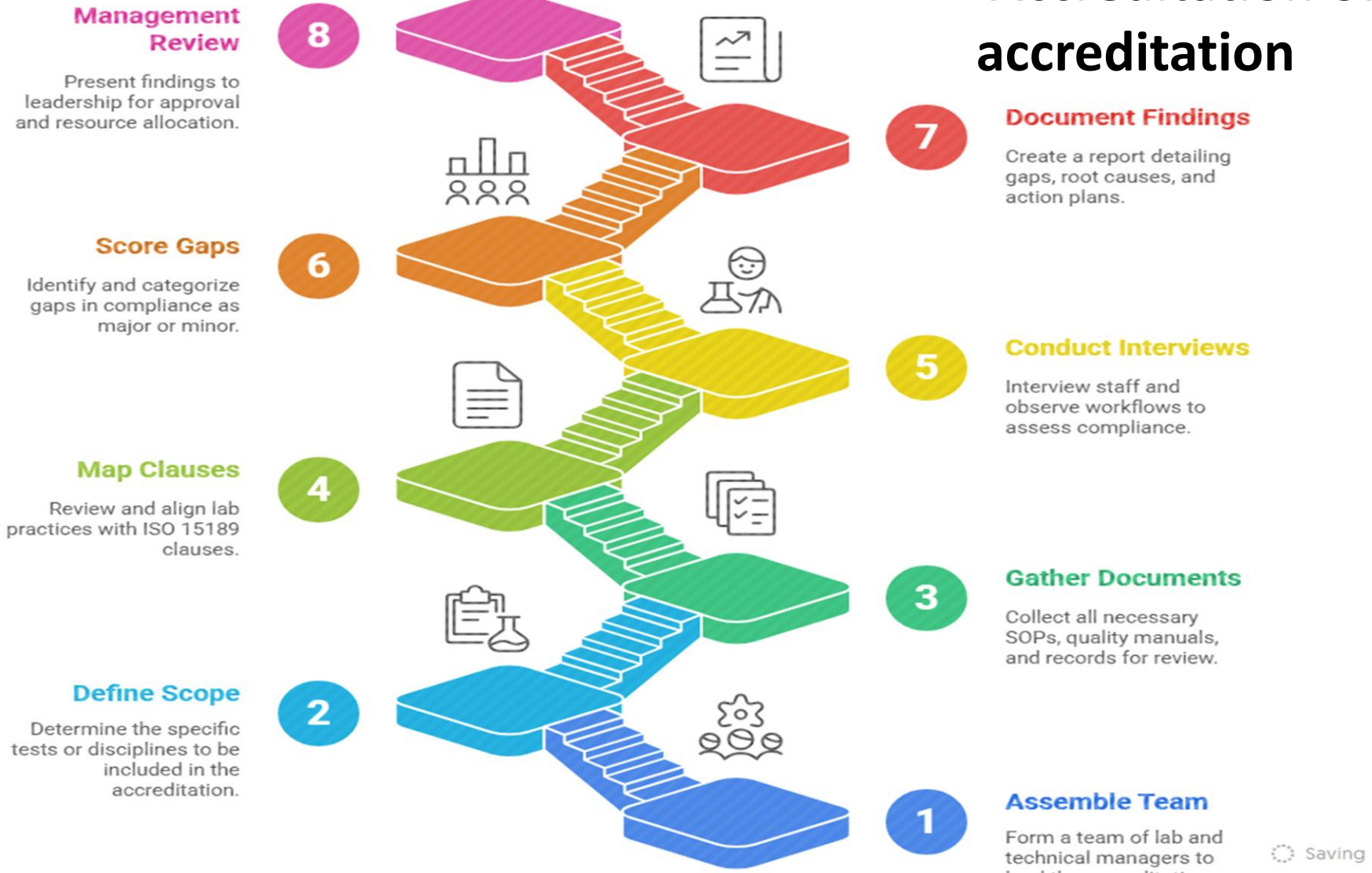
- 1. Commitment from management**
- 2. Gap assessment and baseline evaluation ( what Scope and Why and How?)**
- 3. Formation of Quality Implementation Team ( Quality manager, Tech manager)**
- 4. Development of QMS documents (SOPs, manuals, forms)**
- 5. Training of staff**
- 6. Method validation and verification & Calibration**
- 7. IQC and EQA implementation**
- 8. Internal audit & management review**
- 9. Application for accreditation**
- 10. Pre-assessment by AB**
- 11. Final assessment and accreditation**

## **CHOOSING THE RIGHT ISO STANDARDS**

**Based on the Nature of Laboratory activities, SCOPE , an application for any one of the ISO Standards can be applied**

- **ISO 15189 applies to medical laboratories, emphasizing patient care, clinical risks, and pre/post-examination processes.**
- **ISO/IEC 17025 covers testing and calibration labs across industries, focusing on measurement accuracy and traceability.**
- **ISO/IEC 17043 targets proficiency testing (PT) providers, ensuring impartial interlab comparisons and scheme validity.**

# Gap Analysis & Steps of Accreditation of ISO accreditation



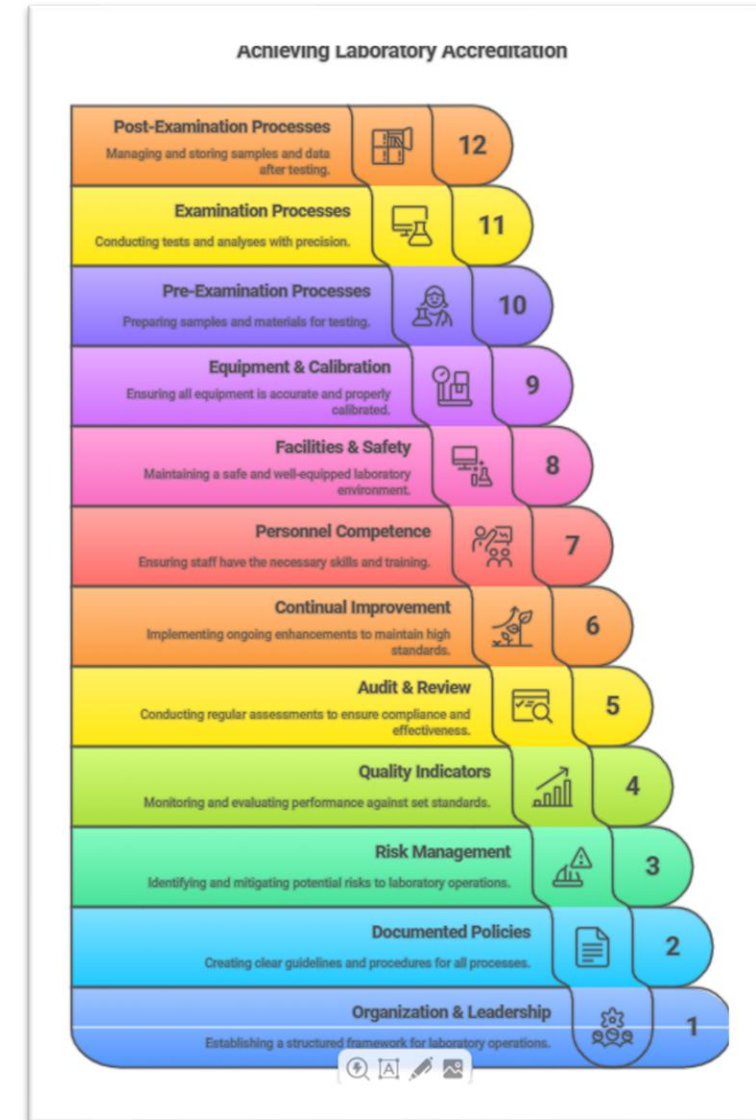
# STRUCTURE OF ISO Accreditation

## A. MANAGEMENT REQUIREMENTS

1. Organization and leadership
2. Documented policies & procedures
3. Risk management
4. Quality indicators
5. Audit & review
6. Continual improvement

## B. TECHNICAL REQUIREMENTS

1. Personnel competence
2. Facilities & safety
3. Equipment & calibration
4. Pre-examination/Testing processes
5. Examination /Testing processes
6. Post-examination/Testing processes
7. Reporting of results
8. Quality assurance (IQC & EQA)
9. Data and information management



# ISO Accreditation - Core Requirements – Management System

## Organizational Structure

- Defined roles: Lab director, quality officer, section heads
- Authority and responsibilities documented

## Document Control

- SOPs, manuals, forms, records
- Version control & approval mechanisms

## Risk Management & Failure Modes

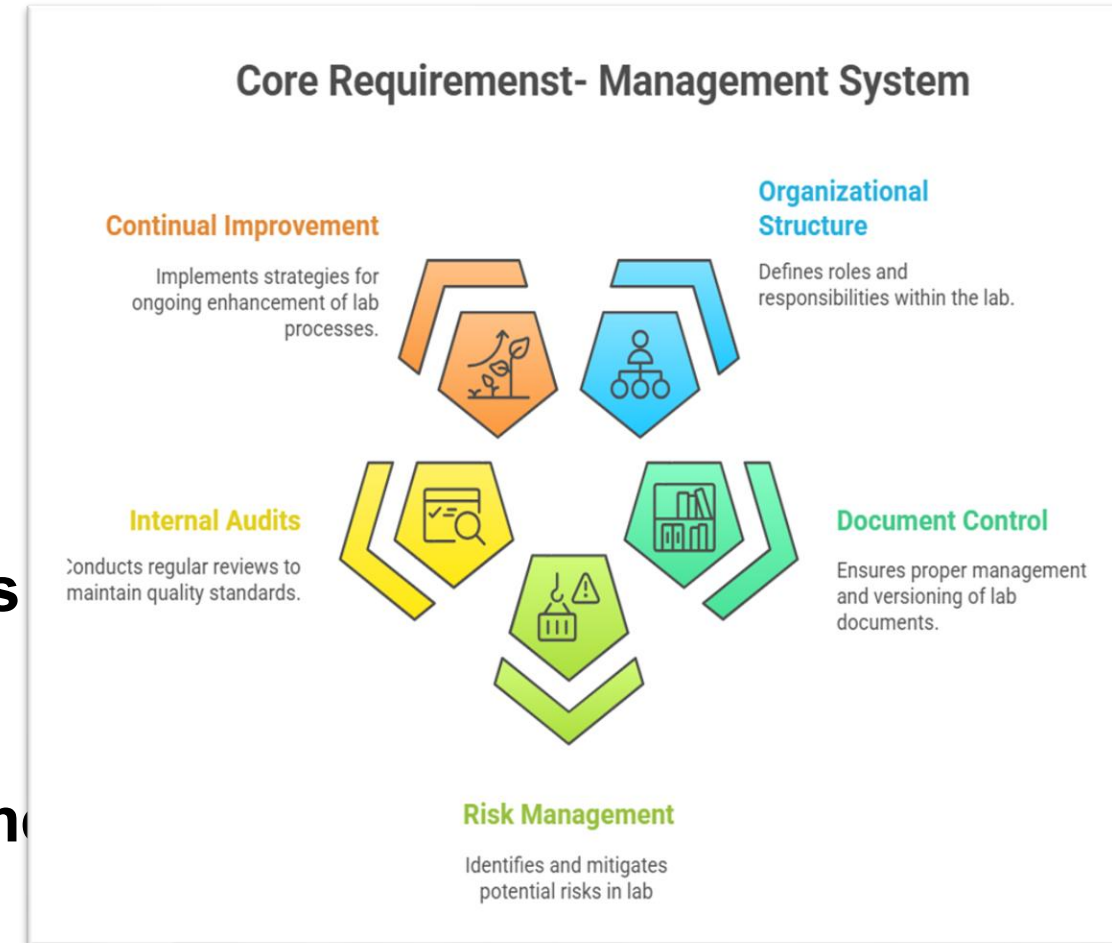
- Identifying risks (eg Equip downtime)
- Risk matrix & Mitigation strategies

## Internal Audits & Management Review

Annual internal audit plan, Review Indicators  
Corrective and preventive actions (CAPA)

## Continual Improvement

- Using proficiency testing results- improvement
- Non-conforming work tracking



# ISO Accreditation Core Requirements – Technical Competence

## Personnel Requirements

- Job descriptions
- Competency assessments
- Scope of authorization
- Ongoing training

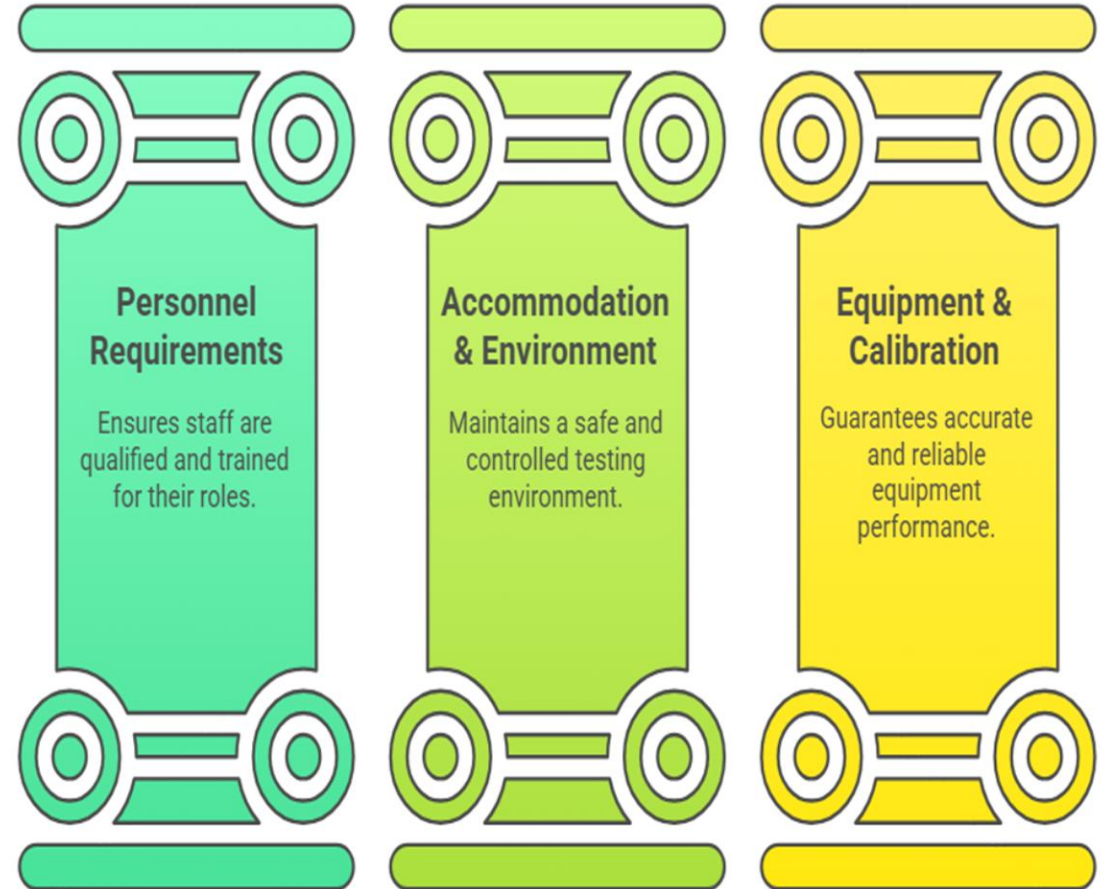
## Accommodation & Environment

- Biosafety
- Controlled areas for testing
- Temperature, humidity, noise, ventilation

## Equipment & Calibration

- Equipment selection
- Calibration and maintenance schedule
- IQ/OQ/PQ
- Metrological traceability
- Pipette calibration

### Core Requirements - Technical Competence



# ISO Accreditation Core Requirements – Technical Competence....

continuation

## Pre-examination/ Testing Process

- Sample collection
- Transport and storage
- Acceptance/rejection criteria
- Patient identification

## Examination/Testing Process

Method verification and validation

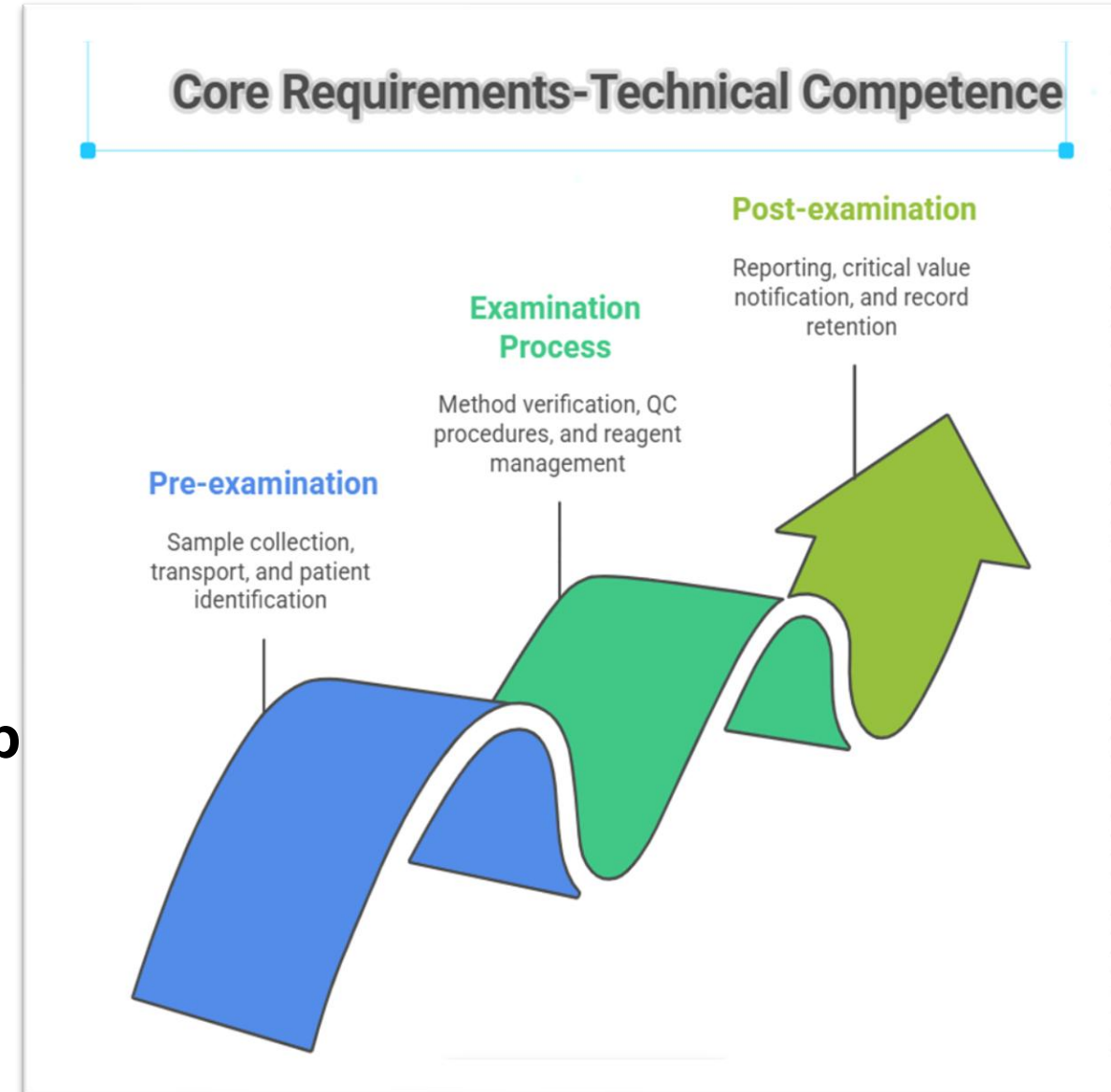
QC procedures

Reagents & consumables management

Uncertainty of measurement (when applicable)

## Post-examination/Testing Process

- Correct reporting format
- Critical values notification
- Record retention
- Interpretation & comments in medical context



## **ISO Accreditation - Common Non-Conformities**

- 1. Incomplete documentation**
- 2. Poor QC/EQA management**
- 3. Missing method validation data**
- 4. Inadequate training/competency records**
- 5. Equipment without proper calibration**
- 6. Incorrect sample handling**
- 7. Missing risk assessments**
- 8. Weak internal audit systems**

**The ISO 15189 latest edition is published in December 2022**  
**So its ISO 15189 : 2022**

**The ISO 17025 latest edition is Published in November 2017**  
**So its ISO 17025 : 2017**

**The ISO 17043 latest edition is published in May 2023**  
**So its ISO 17043 : 2023**

# COMPARATIVE ANALYSIS OF THE THREE STANDARDS

Aspect	ISO 15189	ISO 17025	ISO 17043
Target users	Medical labs	Testing/calibration labs	PT/EQA providers
Focus	Patient care, diagnostics	Technical competence	Inter-lab comparison
Key outcome	Accurate clinical results	Traceable, valid measurements	Reliable PT schemes
Relevance to NRLs	Human health	Human/Animal/Environment testing	Quality assurance

## ISO 15189

## ISO 17025

## ISO 17043

**What  
Labs?**

**Public health labs  
National reference  
laboratories  
Hospital labs  
Molecular and serology  
labs**

**Chemical testing  
Environmental  
testing  
Microbiological  
testing  
Forensic testing  
Calibration of  
instruments**

**International  
standard for  
competence of  
organizations  
providing  
proficiency testing  
(PT)**

# **Scope and Purpose**

<b>Aspect</b>	<b>ISO 15189</b>	<b>ISO 17025</b>	<b>ISO 17043</b>
<b>Main focus</b>	<b>Medical laboratory quality and competence</b>	<b>Testing and calibration laboratory competence</b>	<b>Competence of proficiency testing providers</b>
<b>Typical organization</b>	<b>Medical/ clinical lab</b>	<b>Testing, calibration, sampling lab</b>	<b>PT / interlaboratory comparison provider</b>
<b>Main objective</b>	<b>Reliable patient results, clinical safety</b>	<b>Technically valid test/calibration results</b>	<b>Reliable PT schemes, comparison of participant performance</b>

Category	ISO 15189: Medical Laboratories	ISO 17025: Testing & Calibration Laboratories	ISO 17043: Proficiency Testing Providers
Primary Purpose	Quality & competence requirements for medical laboratories performing patient testing	General competence of testing and calibration laboratories	Requirements for competence of organizations providing proficiency testing (PT)
Scope	Clinical sample testing, patient safety, quality of results, pre-analytical to post-analytical phases	Technical competence, method validation, calibration, measurement traceability	Design, development, operation of PT schemes for labs
Management System Requirements	Similar to ISO 9001; strong focus on clinical governance and risk management	Similar to ISO 9001; focus on impartiality, confidentiality, documentation	Includes ISO 9001 principles; emphasis on PT planning, confidentiality, data integrity

Category	ISO 15189: Medical Laboratories	ISO 17025: Testing & Calibration Laboratories	ISO 17043: Proficiency Testing Providers
Competence of Personnel	Qualifications, ongoing competency, clinical interpretation, training records	Technical competency, authorized signatories, training, supervision	Competency of PT designers, statisticians, technical experts
Facilities & Environmental Conditions	Clinical environment, biosafety, sample handling areas	Environmental control for accurate testing/calibration (temperature, humidity, vibration)	Secure data handling & logistical conditions for PT samples

# **General and structural requirements**

Requirement area	ISO 15189 (keywords)	ISO 17025 (keywords)	ISO 17043 (keywords)
<b>Impartiality</b>	<b>Medical judgment independence, no undue influence</b>	<b>Impartiality policy, risk to impartiality managed</b>	<b>Impartial PT operation, no conflict of interest</b>
<b>Confidentiality</b>	<b>Patient data confidentiality, privacy</b>	<b>Client data and results confidentiality</b>	<b>Participant data confidentiality, coded results</b>
<b>Organization &amp; structure</b>	<b>Defined roles, clinical governance, lab director</b>	<b>Defined legal identity, structure, management</b>	<b>Defined PT provider structure, responsibilities</b>

# **Resource requirements**

Requirement area	ISO 15189	ISO 17025	ISO 17043
<b>Personnel</b>	Qualified healthcare professionals, competence, ongoing training	Competent technical staff, authorization for tasks	Competent PT design, statistics, technical staff
<b>Facilities &amp; environment</b>	Patient-oriented lab layout, biosafety, sample flow	Environmental conditions controlled for tests/calibrations	Facilities suitable for PT item production, storage, dispatch
<b>Equipment</b>	Validated analyzers, maintenance, calibration, metrological traceability	Equipment suitability, calibration, maintenance, metrological traceability	Equipment to prepare, measure, and check PT items

# **Process / technical requirements**

<b>Requirement area</b>	<b>ISO 15189</b>	<b>ISO 17025</b>	<b>ISO 17043</b>
<b>Request &amp; contract review</b>	<b>Clinical request, patient ID, clinical information</b>	<b>Review of requests and contracts with customers</b>	<b>PT scheme design agreed with stakeholders</b>
<b>Pre-examination</b>	<b>Patient prep, specimen collection, transport, acceptance criteria</b>	<b>Sampling plans where relevant, sample handling</b>	<b>PT item production, homogeneity, stability</b>
<b>Examination / testing</b>	<b>Validated methods, verification, measurement uncertainty when applicable</b>	<b>Method validation/verification, measurement uncertainty, quality control</b>	<b>Assignment of reference values, statistical design of PT</b>

Requirement area	ISO 15189	ISO 17025	ISO 17043
<b>Post-examination</b>	Report format, critical values, clinical interpretation, result release	Test/calibration reports content, traceability of results	PT result collection, performance evaluation, scoring
<b>Quality control</b>	Internal QC, EQA participation, risk-based controls	Internal quality control, proficiency testing participation	Internal checks on PT process, monitoring scheme performance

# **Management system requirements**

Requirement area	ISO 15189	ISO 17025	ISO 17043
<b>QMS model</b>	Medical lab QMS aligned with ISO 9001 principles	Laboratory QMS, risk-based, ISO 9001 compatible options	PT provider QMS, process-based, ISO 9001 aligned
<b>Document control</b>	Controlled procedures, forms, clinical guidelines	Controlled policies, procedures, technical records	Controlled PT schemes, instructions, records
<b>Nonconformities &amp; CAPA</b>	Error management, incident reporting, corrective action	Nonconformity control, corrective and preventive actions	Nonconformity in PT activities, corrective actions
<b>Internal audit</b>	Planned audits of all QMS and technical activities	Internal audits covering all requirements	Internal audits of PT processes
<b>Management review</b>	Regular review with clinical, quality, resource data	Review of QMS performance, risks, improvements	Review of PT scheme performance, customer feedback

<b>Equipment Management</b>	<b>Selection, calibration, maintenance, metrological traceability</b>	<b>Detailed requirements: calibration, verification, intermediate checks</b>	<b>Ensuring equipment for PT sample preparation meets quality requirements</b>
<b>Quality Control (Internal QC)</b>	<b>Mandatory: IQC, quality indicators, continual improvement</b>	<b>QC procedures appropriate to testing/calibration</b>	<b>QC relates to PT material production (e.g., homogeneity studies)</b>
<b>External Quality Assessment (EQA)</b>	<b>Participation in EQA/PT mandatory</b>	<b>Participation in PT strongly recommended; sometimes mandatory by regulators</b>	<b>Standard defines how PT is organized for others</b>

<b>Pre-Analytical Requirements</b>	<b>Sample collection, transport, acceptance criteria, identification</b>	<b>Not specifically covered</b>	<b>Not applicable (PT samples only)</b>
<b>Analytical Requirements</b>	<b>Verification/validation of test methods, QC, measurement uncertainty (as applicable)</b>	<b>Method validation, measurement uncertainty, calibration, metrological traceability</b>	<b>Homogeneity &amp; stability of PT materials, assigned values, statistical design</b>
<b>Post-Analytical Requirements</b>	<b>Reporting of patient results, critical value communication, retention, interpretation</b>	<b>Reporting test results, uncertainty reporting, calibration certificates</b>	<b>Evaluation reports to participants, scoring systems</b>

<b>Risk Management</b>	<b>Comprehensive risk-based thinking relating to patient safety</b>	<b>Risk-based approach for impartiality and validity of results</b>	<b>Risks associated with PT design, sample distribution, scoring</b>
<b>Traceability</b>	<b>Medical traceability linked to reference methods/materials</b>	<b>Strong requirement: SI units, reference standards, calibration hierarchies</b>	<b>Traceability of assigned values, reference labs involvement</b>
<b>Nonconforming Work Management</b>	<b>Work affecting patient results, corrective actions</b>	<b>Detection, evaluation, corrective actions</b>	<b>Evaluation of errors affecting PT outcomes</b>

<b>Internal Audits &amp; Management Review</b>	<b>Annual review; includes clinical outcomes, patient feedback</b>	<b>Annual review; technical performance &amp; QC included</b>	<b>Annual review covering PT performance, scheme effectiveness</b>
<b>Customer Focus</b>	<b>Patient-centric; clinician and patient feedback required</b>	<b>Laboratory clients; technical feedback and reporting</b>	<b>Customer = participating laboratories; service transparency</b>
<b>Safety Requirements</b>	<b>Strong emphasis on biosafety, infection control</b>	<b>Safety only as it affects result quality</b>	<b>Safety for PT sample handling and distribution</b>

## **Comparison of three ISO standards in Brief**

## Aspect

**ISO 15189** 

**ISO/IEC 17025** 

**ISO/IEC 17043** 

## Scope

Medical laboratories  
(patient diagnosis &  
care)

Testing & calibration  
laboratories

Proficiency Testing  
(PT) providers

## General Requirements

Ethics, patient  
safety,  
confidentiality,  
impartiality

Impartiality,  
confidentiality,  
reliable results

Impartiality,  
confidentiality, fair  
PT schemes

## Structural Requirements

Defined lab  
leadership & clinical  
responsibility

Defined  
organization,  
authority &  
responsibility

Independent PT  
management &  
decision-making

## Resource Requirements

Qualified staff,  
validated medical  
methods, safe  
facilities

Competent staff,  
calibrated  
equipment,  
validated methods

Skilled PT staff,  
suitable facilities, PT  
materials

## Aspect

ISO 15189 

ISO/IEC 17025 

ISO/IEC 17043 

## Management Requirements

QMS focused on patient care & continual improvement

QMS focused on technical validity & risk management

QMS focused on PT planning, delivery & reporting

## Core Focus

Patient safety & clinical decisions

Accuracy & technical competence

Evaluation of laboratory performance

## One-Line Message

*For labs testing patient samples*

*For labs testing samples*

*For organizations testing labs*

# **ACCREDITATION BODIES**

# SOUTH ASIA

Country	National Accreditation Body (Full Official Name)
Afghanistan	Afghanistan National Standards Authority (ANSA) / Afghanistan Standard & Quality Authority (ASQA)
Bangladesh	Bangladesh Accreditation Board (BAB)
Bhutan	Bhutan Standards Bureau (BSB)
India	National Accreditation Board for Testing & Calibration Laboratories (NABL)
Maldives	No dedicated national accreditation body; labs use regional/international ABs
Nepal	Nepal Accreditation Foundation (NAF)
Pakistan	Pakistan National Accreditation Council (PNAC)
Sri Lanka	Sri Lanka Accreditation Board for Conformity Assessment (SLAB)

## **SOUTH EAST ASIA**

<b>Brunei Darussalam</b>	<b>No standalone national AB; lab accreditation by Min of Development</b>
<b>Cambodia</b>	<b>Cambodian Accreditation National Council / General Department of Accreditation of Cambodia (CANC / GDAC)</b>
<b>Indonesia</b>	<b>(KAN) National Accreditation Body of Indonesia</b>
<b>Lao PDR (Laos)</b>	<b>No single national AB; accreditation thru ministries&amp; regional ABs</b>
<b>Malaysia</b>	<b>Department of Standards Malaysia (SAMM)</b>
<b>Myanmar</b>	<b>Myanmar Accreditation Body (MAB)</b>
<b>Philippines</b>	<b>Philippine Accreditation Bureau (PAB), Department of Trade &amp; Industry (DTI)</b>
<b>Singapore</b>	<b>Singapore Accreditation Council (SAC)</b>
<b>Thailand</b>	<b>Bureau of Laboratory Quality Standards, Department of Medical Sciences (BLQS-DMSc), Ministry of Public Health</b>
<b>Timor-Leste (East Timor)</b>	<b>No national AB; accreditation typically obtained via regional/international ABs</b>
<b>Vietnam</b>	<b>Bureau of Accreditation (BoA), Ministry of Science &amp; Technology</b>

## **EAST ASIA**

<b>China</b>	<b>China National Accreditation Service for Conformity Assessment (CNAS)</b>
<b>Japan</b>	<b>Japan Accreditation Board (JAB)</b>
<b>South Korea</b>	<b>Korea Laboratory Accreditation Scheme (KOLAS)</b>
<b>Mongolia</b>	<b>Mongolian Agency for Standardization and Metrology (MASM) – Accreditation Dept.</b>
<b>Taiwan*</b>	<b>Taiwan Accreditation Foundation (TAF)*</b>

## **OCEANIA -PACIFIC**

<b>Australia</b>	<b>National Association of Testing Authorities (NATA)</b>
<b>New Zealand</b>	<b>International Accreditation New Zealand (IANZ)</b>
<b>Papua New Guinea</b>	<b>No national AB; laboratories use NATA (Australia) or IANZ (New Zealand)</b>

# Accreditation bodies for African Regions

<b>Country / Region</b>	<b>Accreditation Agency</b>
<b>South Africa</b>	<b>South African National Accreditation System (SANAS)</b>
<b>Kenya</b>	<b>Kenya Accreditation Service (KENAS)</b>
<b>Ethiopia</b>	<b>Ethiopian National Accreditation Office (ENAO)</b>
<b>Egypt</b>	<b>Egyptian Accreditation Council (EGAC)</b>
<b>Mauritius</b>	<b>Mauritius Accreditation Service (MAURITAS)</b>
<b>Nigeria</b>	<b>Nigeria National Accreditation System (NiNAS)</b>
<b>Tunisia</b>	<b>Tunisian Accreditation Council (TUNAC)</b>
<b>Sudan</b>	<b>Sudanese Accreditation Council (SDAC)</b>
<b>Ghana</b>	<b>Ghana National Accreditation Service (GhaNAS)</b>
<b>Rwanda</b>	<b>Rwanda Accreditation System (RWS)</b>
<b>Morocco</b>	<b>Moroccan Accreditation Service (SEMAC)</b>
<b>Algeria</b>	<b>Algerian Accreditation Body (ALGERAC)</b>
<b>West Africa (UEMOA States)</b>	<b>Système Ouest Africain d'Accréditation (SOAC)</b>
<b>Southern Africa (SADC States)</b>	<b>SADC Accreditation Service (SADCAS)</b>
<b>Africa (Continental Coordination)-</b>	<b>African Accreditation Cooperation (AFRAC)</b>

# **SOFTWARES IN ISO ACCREDITATIONS**

## ISO 15189 SOFTWARE BY REGION

Region	Common Software	Key Features/Notes
South Asia (India)	MocDoc LIMS, PathLIMS, Erba LIMS, Cloud LIMS	NABL-compliant; ABDM/HL7 FHIR support, audit trails <a href="#">pathlims+2</a>
Southeast Asia	Eusoft.Lab, Dedalus KaliLab	Malaysian/Thai labs; workflow validation <a href="#">eusoft+2</a>
East Asia (Korea/Japan)	LabVantage, MocDoc variants	QMS integration, local accreditation <a href="#">labvantage+1</a>
Oceania/Pacific	Thermo Fisher SampleManager	NATA-aligned for NZ/Australia <a href="#">thermofisher</a>

## ISO 17025 SOFTWARE BY REGION

Region	Common Software	Key Features/Notes
South Asia (India)	MocDoc LIMS, PathLIMS	Traceability for NABL 17025 scopes <a href="#">mocdoc+1</a>
Southeast Asia	SafetyCulture, local QMS	SAC Singapore audits, checklists <a href="#">b2bcert+1</a>
East Asia	LabVantage, Erba LIMS	JABLA/JAS-ANZ compliant <a href="#">factocert+1</a>
Oceania/Pacific	Matrix Gemini, SampleManager	NATA accreditation support <a href="#">autoscribeinformatics+2</a>

## ISO 17043 SOFTWARE BY REGION

Region	Common Software	Key Features/Notes [web:id]
South Asia	QuoData PROLab, custom PT tools	APLAC PT schemes <a href="#">quodata+2</a>
Southeast Asia	TAF-accredited PT software	Taiwan/Indonesia providers <a href="#">taftw</a>
East Asia	QuoData solutions	Regional proficiency testing <a href="#">quodata</a>
Oceania/Pacific	NATA/IANZ PTP tools	Custom for accredited schemes
African region	OpenELIS • Bika LIMS • STARLIMS	

## Software for African regions

### ISO 15189 (Medical Labs)

OpenELIS

Bika LIMS

STARLIMS

LabWare LIMS

MasterControl

QT9 QMS

ISOTools

SharePoint

iAuditor

### ISO/IEC 17025 (Testing & Calibration)

Bika LIMS

LabWare LIMS

STARLIMS

iLab

GAGEtrak

Caliber

Asset Panda

MasterControl

QT9 QMS

### ISO/IEC 17043 (Proficiency Testing)

EPTIS Portal

OneWorld Accuracy

QAP PT Systems

LGC PT Portals

PT Provider Web Portals

In-house PT Software

Excel-based PT Tracking

STARLIMS

LabWare LIMS

## Top LIMS by Standard and Region

ISO Standard	Top LIMS	Regions of Wide Use	Key Adoption Notes [web:id]
ISO 15189	MocDoc LIMS	South Asia (India), SE Asia (Malaysia, Thailand), East Asia (Korea), Oceania	NABL/SAC leader; cloud scalability, HL7 FHIR <a href="#">linkedin+2</a>
ISO 17025	PathLIMS	South Asia (India), SE Asia (Singapore), Oceania (Australia/NZ), East Asia	NABL/NATA workflows, traceability for SMEs <a href="#">pathlims+1</a>
ISO 17043	QuoData PROLab  OpenELIS • Bika LIMS	South/SE/East Asia, Oceania-Pacific  African Region	PT scheme management across APLAC/NATA providers

# **APPLICATION TO ACCREDITATION**

# Start

Laboratory identifies ISO standard and conducts gap analysis

## Application Review & Contract

AB reviews application, signs contract, and proposes assessment plan

## Pre-Assessment (Optional)

On-site or remote readiness assessment identifies major gaps

## Non-Conformity Reporting

AB issues report classifying major and minor non-conformities

## Verification of Corrective Actions

AB verifies effectiveness of corrective actions and closes NCs



## Brand Studio Grant of Accreditation

Accreditation certificate issued and scope published



Share



## Application Submission

Formal application, scope, and quality manual submitted to AB

## Documentation Review

AB assesses quality manual, SOPs, and records for compliance

## On-Site Assessment

AB team evaluates technical competence, staff, equipment, and methods

## Corrective Action & Root Cause Analysis

Laboratory analyzes root causes and submits corrective action plan

## Accreditation Decision

Independent committee reviews assessment and corrective action evidence

## Surveillance & Re-Assessment

Annual surveillance and re-accreditation cycle maintains compliance



### Step 1: Enquiry & Awareness

- Laboratory identifies relevant ISO standard (15189 / 17025 / 17043)
- Preliminary gap analysis against standard requirements
- Selection of appropriate Accreditation Body (AB)



### Step 2: Application Submission

- Formal application submitted to Accreditation Body
- Scope of accreditation defined (tests, parameters, methods)
- Application fee paid
- Quality Manual and key documents submitted



### Step 3: Application Review & Contract

- Accreditation Body reviews application completeness
- Scope feasibility and assessor availability checked
- Accreditation agreement / contract signed
- Assessment plan proposed

### Step 4: Documentation Review (Stage 1 Assessment)

- Review of Quality Manual, SOPs, policies, records
- Evaluation of compliance with ISO clauses
- Identification of documentation gaps or concerns
- Laboratory addresses preliminary observations (if any)



### Step 5: Pre-Assessment (Optional but Recommended)

- On-site or remote readiness assessment
- Identification of major gaps before final assessment
- Corrective actions initiated (non-mandatory stage)

↓  
**Step 6: On-Site Assessment (Stage 2 Assessment)**

- Assessment team visits laboratory
- Opening meeting with management
- Evaluation of:
  - Technical competence
  - Staff qualifications & training
  - Equipment & calibration
  - Test methods & validation
  - Quality control & PT participation
  - Biosafety, biosecurity, risk management
- Witnessing of tests / activities
- Interviews with staff
- Closing meeting conducted

↓  
**Step 7: Non-Conformity (NC) Reporting**

- Non-conformities classified:
  - Major NCs
  - Minor NCs
- Assessment report issued by Accreditation Body

↓  
**Step 8: Corrective Action & Root Cause Analysis**

- Laboratory conducts root cause analysis
- Corrective action plan submitted
- Objective evidence provided (records, SOPs, training, calibration)

↓  
**Step 9: Verification of Corrective Actions**

- Desk review or follow-up visit by assessors
- Confirmation of effectiveness of corrective actions
- Closure of all non-conformities

↓ **Step 10: Accreditation Decision**

- Independent accreditation decision committee review
- Decision based on:
  - Assessment report
  - Corrective action evidence
  - Scope compliance
- Approval / deferral / rejection decision made



**Step 11: Grant of Accreditation**

- Accreditation certificate issued
- Approved scope published on AB website
- Permission to use accreditation symbol granted



**Step 12: Surveillance & Re-Assessment**

- Periodic surveillance assessments (usually annually)
- Continuous compliance monitoring
- Re-accreditation cycle (typically every 3–4 year)

## FAQs

### **Which standard applies to a National Reference Laboratory (NRL)?**

•If the NRL primarily performs **clinical/diagnostic** testing for patients or public-health diagnosis → ISO 15189. If it performs broad **testing/calibration** services (environmental, food, chemical, instrument calibration) → ISO/IEC 17025. NRLs with multiple roles may need both ISO standards or choose the most relevant scope

### **How do ISO 15189 and ISO/IEC 17025 differ?**

•ISO 15189 is **medical-lab specific** and adds patient-centered requirements (clinical consultations, sample referral, result interpretation, medical confidentiality). ISO/IEC 17025 is **generic** for testing/calibration labs and focuses more on technical traceability.

### **How important is traceability?**

Critical. Results must be traceable to SI units, reference materials, or internationally accepted references where available. Maintain calibration and reference-material records

### **Can academic staff (PhD researchers) count toward technical competence?**

Yes — technical competence is demonstrated by records of training, supervised experience, method competence, and internal assessment — not by titles alone.

Document supervision and competency evidence for students/postdocs doing accredited work.

## FAQs

### How to manage research workflows vs accredited routine testing?

• Maintain **separate documented workflows** or clear stepwise controls (e.g., separate SOPs, sign-offs, data flags) when research or developmental methods are used. Where research results feed into patient/public-health decisions, ensure validated procedures and documentation

### What happens after an audit nonconformity?

Raise corrective action, investigate root cause, implement corrections, and document effectiveness. Accreditation bodies expect timely, documented corrective actions and follow-up

### Biosafety and sample handling — is this covered by the standards?

Yes. ISO 15189 (medical labs) has explicit requirements for specimen handling, biosafety and chain of custody. 17025 requires controlled environments and safe sample handling appropriate to the tests. Link QMS to biosafety procedures

### Do I need method validation or verification?

Yes. For both 17025 and 15189, **validated/verified methods** are required for intended use. Validation evidence should cover accuracy, precision, specificity, LOQ/LOD where applicable, and uncertainty where relevant

Thanks so much for the opportunity to Interact with Researchers from  
Diverse discipline of wider Geography

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Thanks much for your support

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