



# ISO/IEC 17025 Beyond Compliance: The Hidden Drivers of Laboratory Credibility

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*Perry Johnson Laboratory Accreditation, Inc.*

# About PJLA

## **Perry Johnson Laboratory Accreditation, Inc. (PJLA)**

Established in 1999 by Mr. Perry L. Johnson

Headquartered in Troy, Michigan.

More than 2300 accreditations globally in 32 countries.

## **Perry Johnson Laboratory Accreditation NP, Inc. (PJLANP)**

Michigan nonprofit organization established in 2016.



Perry L. Johnson

Member and signatory of APAC, ILAC MRAs



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*Perry Johnson Laboratory Accreditation, Inc.*

# PJLA's Global Network



*Perry Johnson Laboratory Accreditation, Inc.*

# PJLA Accreditation Programs

## ISO/IEC 17025

### Testing/Calibration Labs

- FCC OET Equipment Authorization
- FDA ASCA
- ENERGY STAR
- Cannabis Testing
- Hemp Testing
- Horseracing Laboratories Program
- CPSC
- AS6171A Testing
- Food, Feeds, and Pharmaceutical:  
*AOAC, AAFCO, LAAF*
- Environmental Testing: *TNI-NEFAP, DoD ELAP, DOECAP-AP, EPA NLLAP*  
*TNI-EL: MNELAP, CA ELAP, LELAP*

**ISO/IEC 17020** – Inspection Bodies

**ISO/IEC 17065** – Product Certification Bodies

**ISO/IEC 17043** – Proficiency Testing Providers

**ISO 17034** – Reference Material Producers

**ISO 15189** – Medical Laboratories

**ISO/IEC 17024** – Personnel Certification Bodies

**ASTM E2659**– Training Providers



# What We Will Cover

- Why compliance alone is not enough
- What truly builds laboratory credibility
- Hidden technical and operational risks
- Competence and technical integrity
- Method verification and validation
- Measurement uncertainty and traceability
- Data integrity and digital risks
- Lessons from assessments and real-world failures
- Future challenges for laboratories

# The Central Question: Are Accredited Laboratories Always Trusted?

Many laboratories achieve accreditation.

Far fewer achieve long-term technical credibility.

Customers, regulators, and stakeholders ultimately evaluate labs based on:

- Reliability of results
- Consistency
- Technical judgment
- Responsiveness
- Integrity
- Confidence under pressure

**Compliance may open the door - Credibility determines reputation**



# What ISO/IEC 17025 Actually Requires – The Foundation of Competence

## ISO/IEC 17025 addresses:

- Technical competence
- Management system effectiveness
- Validity of results
- Impartiality
- Consistent operation

## Key principles include:

- Competent personnel
- Suitable facilities and equipment
- Valid methods
- Traceable measurements
- Reliable reporting

**Standards define minimum expectations - Excellence requires more**

# The Difference Between Compliance and Credibility

## Compliance

- Documents exist
- Procedures are implemented
- Requirements are addressed
- Audits are passed

## Credibility

- Results are trusted
- Technical decisions are respected
- Customers return with confidence
- Problems are identified before failure occurs
- Personnel demonstrate scientific discipline

**A laboratory can be compliant and still not fully credible**

# The Hidden Drivers of Credibility – What Truly Builds Confidence

## Core Drivers

- Technical competence
- Scientific integrity
- Consistency of operations
- Data reliability
- Strong technical leadership
- Effective risk management
- Transparent decision-making
- Robust quality culture
- Reliable communication
- Continuous improvement mindset

**A laboratory can be compliant and still not fully credible**



# Personnel Competence – The Most Important Variable

## *Laboratories Depend on People*

Even advanced laboratories fail when:

- Training is superficial
- Authorization is weak
- Competence is assumed
- Technical judgment is inconsistent
- Experience is not transferred

## Key Questions

- Can personnel explain the science behind the method?
- Can they identify anomalies?
- Can they defend technical decisions?
- Can they recognize invalid results?

**Competence is demonstrated - not declared**



# Competence Drift – A Hidden Risk in Laboratories

## Common Causes

- Repetitive routine testing
- Lack of technical challenges
- Infrequent oversight
- Poor refresher training
- Staff turnover
- Overreliance on automation



## Result

Personnel continue operating systems correctly while gradually losing deep technical understanding.

**This is one of the most overlooked risks in accredited laboratories**

# Method Verification vs Validation – One of the Most Misunderstood Areas

## Verification

*“Can our laboratory properly perform this established method?”*

## Validation

*“Does this method actually work for the intended purpose?”*

## Frequent Problems

- Confusing verification with validation
- Insufficient performance studies
- Inadequate acceptance criteria
- Poor statistical justification
- Weak documentation of technical rationale

**Not Just Read - Understand the Standard**



# Measurement Uncertainty – Confidence in Numerical Results

*Measurement uncertainty is not a paperwork exercise.*

It directly affects:

- Decision rules
- Product acceptance
- Regulatory compliance
- Customer confidence
- Risk exposure

## Common Weaknesses

- Unrealistic uncertainty budgets
- Missing contributors
- Incorrect statistical assumptions
- Poor understanding by personnel

**Poor uncertainty evaluation can undermine otherwise excellent technical work**

# Metrological Traceability – The Invisible Backbone of Trust

## Traceability Ensures:

- Comparability of measurements
- International confidence
- Reliable calibration chains
- Defensible technical decisions

## Common Risks:

- Unverified reference materials
- Incorrect calibration intervals
- Incomplete traceability chains
- Misunderstanding of traceability requirements

**Without traceability, confidence collapses**



# Data Integrity – The New Technical Battlefield

## Laboratories Are Increasingly Digital

Risks now include:

- Unauthorized data modification
- Weak electronic controls
- LIMS vulnerabilities
- Cybersecurity risks
- Inadequate backup systems
- AI-generated data concerns

**Critical Question: *Can the laboratory demonstrate that its data is accurate, protected, complete, and trustworthy?***

# Risk-Based Thinking: Preventing Failure Before It Happens

ISO/IEC 17025 introduced stronger emphasis on risk-based thinking.

## Effective Laboratories:

- Anticipate technical failures
- Identify weak controls early
- Monitor operational vulnerabilities
- Learn from near misses
- Treat complaints as improvement opportunities

**Risk management is a credibility tool - not merely a compliance requirement**



# Internal Audits – Are They Improving the Laboratory?

## Weak Internal Audits Often:

- Follow checklists mechanically
- Ignore technical depth
- Focus on documentation only
- Miss systemic issues

## Effective Internal Audits:

- Challenge technical assumptions
- Evaluate effectiveness
- Examine real technical risks
- Verify competence in practice
- Identify improvement opportunities

**Probably, the most powerful improvement tool**

# Proficiency Testing – What PT Really Reveals

PT participation is more than a requirement.

It reveals:

- Technical consistency
- Method performance
- Staff capability
- Measurement reliability
- Comparability with peers

**Important Reality: Good PT performance does not guarantee competence - But repeated poor PT performance almost always indicates deeper systemic issues.**

# Why Accredited Laboratories Fail – Common Root Causes

## Repeated Causes Seen Worldwide

- Weak technical leadership
- Poor competence management
- Overdependence on paperwork
- Inadequate method control
- Data integrity failures
- Weak corrective action processes
- Cultural resistance to improvement
- Commercial pressure overriding science

**Most laboratory failures begin long before they become visible**

# The Role of Laboratory Culture – Technical Integrity Matters

## Strong Laboratory Cultures Encourage:

- Scientific discipline
- Openness about errors
- Technical questioning
- Ethical behavior
- Continuous learning
- Transparent communication

## Weak Cultures Encourage:

- Shortcut behavior
- Fear of reporting issues
- Blind procedural compliance
- Data manipulation risks

**Culture ultimately shapes credibility**



# Customers Do Not Audit Clauses – They Judge Confidence

Customers evaluate laboratories based on:

- Reliability under pressure
- Timeliness
- Technical responsiveness
- Professionalism
- Confidence in results
- Ability to explain findings

**Laboratories are trusted when they consistently demonstrate competence in real situations**



# Remote Assessments and Digital Laboratories – The Future Challenge

## Emerging Trends

- Remote witnessing
- Digital records
- AI-supported analysis
- Cloud-based systems
- Automated laboratories
- Hybrid assessments

## New Questions

- How do we verify authenticity?
- How do we ensure data integrity remotely?
- How do we evaluate competence in digital environments?

**Technology changes tools.  
It does not remove the need for technical credibility.**



# What Differentiates Great Laboratories? – Characteristics of High-Credibility Laboratories

## High-Performing Laboratories:

- Invest heavily in competence
- Encourage technical curiosity
- Treat quality as scientific discipline
- Learn from failures rapidly
- Prioritize integrity over convenience
- Maintain strong technical leadership
- Focus on reliability, not appearances

**They move beyond accreditation!**  
**They become trusted technical institutions.**



# Choosing your Accreditation Body (1/2)

Choosing an accreditation body is not simply an administrative decision. It is a strategic decision that can significantly influence:

- Market credibility
- Regulatory acceptance
- Customer confidence
- Assessment experience
- Long-term operational flexibility
- International recognition

**Not All Accreditation Experiences Are the Same!**



# Choosing your Accreditation Body (2/2)

## Important Factors to Evaluate:

- International recognition and MLA status
- Recognitions by regulators
- Technical competence of assessors
- Consistency and professionalism
- Responsiveness and customer support
- Transparency of processes and fees
- Understanding of laboratory operations
- Ability to support evolving scopes and technologies

**Not All Accreditation Experiences Are the Same!**



# Key Takeaways – Final Messages

- Accreditation is essential but not sufficient
- Technical competence must be continuously demonstrated
- Credibility is built through integrity and consistency
- People remain the most critical factor
- Data reliability is becoming increasingly important
- Strong laboratory culture drives long-term trust
- Continuous improvement must remain technical, not bureaucratic
- Accreditation should add value, not unnecessary bureaucracy.

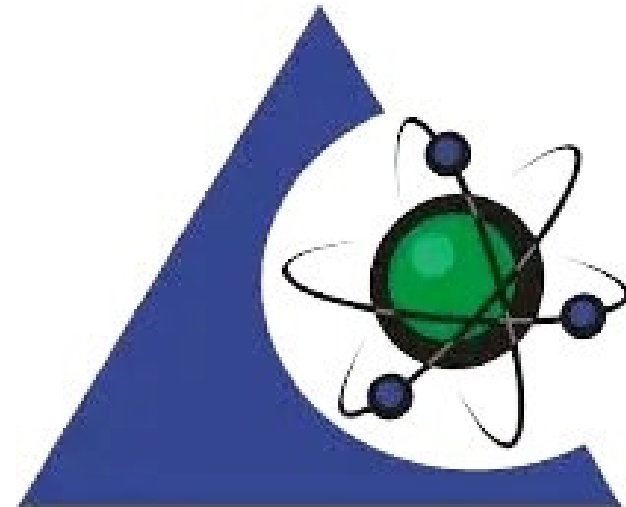
**The ultimate product of a laboratory is CONFIDENCE**



# Thank You!

- Questions
- Discussion

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