



# How to Be Audited

## Turn Your Next Accreditation Assessment into a Positive Experience!

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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 2200 accreditations globally in 32 countries.



Perry L. Johnson

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

Michigan nonprofit organization established in 2016.

Member and signatory of APAC, ILAC MRAs



# 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, DOE CAP-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

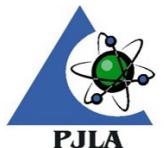


# Introduction-Why This Webinar Matters

Even highly experienced MS Professionals still feel:

- Stress before the assessment/audit
- Pressure during assessment/audit interviews
- Fear of nonconformities
- Uncertainty about what auditors/assessors want
- Concern about “being judged”

*This webinar exists because very few people are ever trained on how to be audited, yet everyone is eventually audited.*



# Auditor vs Assessor (Audit vs Assessment)

An **Auditor** operates at the certification level and evaluates whether an organization's management system conforms to the requirements of a specified standard (e.g. ISO 9001).

**Auditors** typically work for certification bodies or internal audit programs and provide findings that support a certification decision.

An **Assessor** operates at the accreditation level and evaluates technical competence of a CAB.

Assessors work for accreditation bodies and determine whether a CAB can produce valid and reliable results, supporting an accreditation decision.

**BOTH** focus on processes, implementation, control, and effectiveness.

**NOTE: For the purpose of this webinar both terms will be used interchangeably.**



# What Makes Assessments Stressful?

- The presence of an “external authority”
- Fear of exposing weaknesses
- Lack of clarity about assessment flow
- Misunderstanding assessor expectations
- Organizational culture (blame vs learning)
- Past negative experiences with other ABs or CABs



# The Real Purpose of the Assessment

## To ensure:

- Competence
- Impartiality
- Consistency
- Technical validity of results
- Market confidence
- COMPLIANCE

## It is NOT:

- Policing
- Punishment
- Perfection checking
- Consult
- Issue Non-Conformities
- A bureaucratic exercise

**It is a trust-building mechanism.**



# How Assessors Actually Think

## Assessors look for:

- Reliable processes
- Competent personnel
- Repeatable outcomes
- Objective decision-making
- Controlled documentation
- COMPLIANCE

## Assessors do not look for:

- Blame
- Perfection
- Catch people out
- Personal weaknesses
- “Tricks” or surprises
- Prove assessor/auditor superiority

**Assessment exists to build confidence,  
verify competence and strengthen trust.**



# Step 1: Preparing Your Documentation

**Documentation should tell a clear story:**

Your system is:

- ✓ Under control
- ✓ Implemented
- ✓ Maintained
- ✓ Updated
- ✓ Understood by staff

**Additional preparation tips:**

- Use record-access shortcuts or digital folders
- Pre-stage key evidence (calibration, competence, internal audits)
- Ensure version control across all documents
- Double-check that obsolete documents are removed

**Be well-prepared. Self-evaluate on AB/CB checklist (if available)**



# Step 2: Demonstrating Competence

## Personnel should be able to answer:

- ✓ “**What** are you doing?”
- ✓ “**Why** are you doing it this way?”
- ✓ “**What** standard or procedure requires this?”
- ✓ “**How** do you know that...?”

## Additional preparation tips:

- Be-prepared, mock questions
- Identify your week points
- Perform “real” internal audits
- Demonstrating impartiality
- Awareness of risks

**Understand your Processes. Modern Assessment is Process based!**



# Step 3: Handling Questions the Right Way

## Do:

- ✓ Be concise
- ✓ Refer to documented evidence
- ✓ Admit when unsure
- ✓ Ask for clarification
- ✓ Stay calm and factual

## Avoid:

- Guessing
- Over-explaining
- Getting defensive
- Talking too much
- Making promises on the spot
- Reply if not asked!
- Respond instead of others

## Know Processes-Procedures-SOPs



# Step 4: Why Nonconformities Are Not Failures

**Nonconformities** provide:

- Insight into system weaknesses
- Opportunities to strengthen process consistency
- Evidence of mature internal culture
- Risk reduction before clients notice issues

A good assessment does NOT necessarily mean zero NCs.

A good assessment ends with valuable insight.

**Nonconformities = free expert consulting!**



# Hiding Nonconformities: The Silent Killer

Hiding issues leads to:

- Loss of trust
- Escalated findings later
- Misalignment with impartiality requirements
- Increased risk before regulators
- Negative impact on reputation

Transparency demonstrates:

- Professional maturity
- Strong culture
- Seriousness about improvement

**Nonconformities = Improvement Opportunity**



# Step 5: Responding to NCs Professionally

When receiving a NC:

- Listen fully
- Ask for wording clarification
- Review evidence together with assessor
- Accept the finding if justified
- Avoid unnecessary debate
- Understand the appropriate root cause analysis
- Implement corrective actions

**Invest time and effort in Root Cause Analysis**



# Step 6: Leadership's Critical Role

Top management expectations:

- Commitment, Commitment, Commitment!
- Understanding of system performance
- Presence at meetings
- Support for competence and resources
- A culture of honesty
- Dedication to improvement

**Assessors can detect leadership disengagement instantly**



# Step 7: Assessment Day Optimization

## Practical Considerations:

- Clean, organized workspace for assessors
- Pre-printed visitor badges & Wi-Fi access
- Structured and clear “evidence table”
- A liaison who coordinates smoothly
- A staff briefing held 24 hours before the assessment

**Professionalism begins with logistics!**



# Step 7: Assessment Day Optimization/Evidence table

ISO/IEC 17025 Clause	Process	Evidence Type	Evidence Description	Location / System	Responsible
8.3	Document control	Procedure	Procedure for control of documents	QMS-PR-01 (SharePoint)	Quality Manager
7.7	Assuring validity of results	Records	Internal QC charts (last 6 months)	LIMS → QC module	Technical Manager
6.2	Personnel competence	Records	Training matrix & competence evaluations	HR folder / LMS	HR Manager
7.5	Technical records	Records	Test worksheets & raw data	LIMS → Job files	Lab Supervisor
8.8	Internal audits	Records	Audit program, reports, NCs, actions	QMS-AUD folder	Lead Internal Auditor
8.9	Management review	Records	Minutes & action tracking	QMS-MR folder	Top Management



# Typical Mistakes Auditees Make

- ✗ Searching for documents in panic
- ✗ Letting unprepared staff respond
- ✗ Guessing answers
- ✗ Treating NCs as punishment
- ✗ Not asking for clarification
- ✗ Blaming past staff
- ✗ Over-defensive attitude
- ✗ Saying “this is how we’ve always done it”



# Good Practices

- ✓ Clear answers
- ✓ Evidence ready
- ✓ Professional tone
- ✓ Transparency
- ✓ Active leadership
- ✓ Clean records
- ✓ Informed personnel
- ✓ Updated documentation
- ✓ Systemic thinking

The goal is NOT perfection.

The goal is:

- ✓ Confidence
- ✓ Trust
- ✓ Consistency
- ✓ Competence
- ✓ Improvement
- ✓ Professionalism

**Assessment is a professional partnership, not a confrontation or debate opportunity**



# Final Thoughts

A successful assessment is built on:

- Preparation
- Clarity
- Transparency
- Strong culture
- Open communication
- Understanding
- Professionalism

**When approached correctly, the assessment becomes a solid improvement tool**



# Thank You!

- Questions
- Discussion

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