



# All You Want to Know About Conformity Assessment Schemes (Relax, It's Legit!)

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

Michigan nonprofit organization established in 2016.



Perry L. Johnson

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, 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



# Introduction–Why This Webinar Matters

Conformity Assessment Schemes are the foundation of trust in certification, accreditation, and regulatory systems. They:

- Establish the set of rules and procedures to verify that specific requirements are met
- Enable global acceptance of results
- Ensure consistency across CABs
- Provide confidence to regulators, industry, and consumers

Yet, many professionals operate within schemes daily but lack a complete understanding of their structure and governance

👉 This webinar bridges that gap.



# Examples

## **Product Certification (e.g., CE Marking)**

The CE Mark is a mandatory conformity assessment scheme for products sold within the European Economic Area.

It signals that a product meets specific EU safety, health, and environmental requirements.

## **Certification of Persons (IPC-PL-11-006)**

IPC Certification Scheme 'IPC Management System Auditors', has been endorsed as a sub-scope for Certification of Persons in the IAF (Global ACI) MLA Scope.



# The “Scheme” Paradox

The word “scheme” creates confusion, especially in American English, often associated with “fraud” or manipulation!

But technically, it means ► A structured system or framework

Origin: Greek σχήμα (schēma) = structure, form, arrangement

ISO meaning is neutral, technical, and foundational:

***A formalized framework of rules and procedures***

👉 Conclusion: Schemes are not suspicious! They are essential structures of trust



# What is a “Conformity Assessment Scheme”

According to ISO terminology (ISO/IEC DIS 17067 ed.2) a **Conformity Assessment Scheme** is a **set of rules and procedures** that:

- Defines the object of conformity assessment
- Identifies specified requirements
- Provides the methodology for assessment

👉 It is NOT:

- Just a standard

It is the **complete operational framework**

# Where Do Schemes Exist?

Schemes are embedded across all conformity assessment activities:

- Certification of persons → ISO/IEC 17024
- Product certification → ISO/IEC 17065
- Management systems → ISO/IEC 17021-1
- Inspection → ISO/IEC 17020
- Testing → ISO/IEC 17025\*
- Accreditation → ISO/IEC 17011

👉 Every accredited activity operates **within a scheme**

\* **Statement of Conformity (Clause 7.8.7):** When a customer requests a "pass/fail" or "in tolerance" result, the laboratory must use a defined **scheme**/decision rule that accounts for measurement uncertainty to make this judgment.

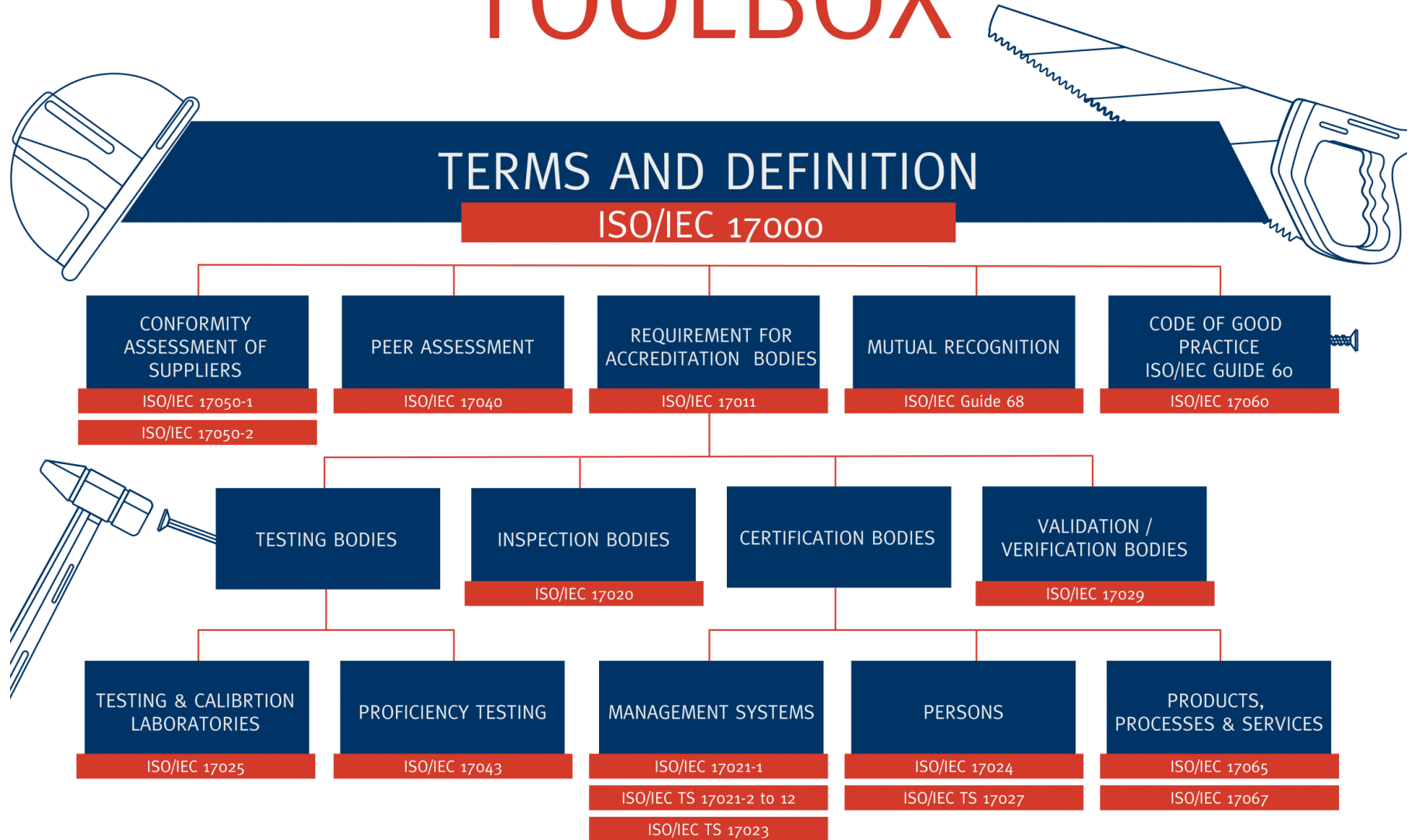


# CASCO Toolbox & Schemes

The ISO/CASCO Toolbox provides the **global architecture** for schemes:

- [ISO/IEC 17067:2013](#): Fundamentals and guidelines for product certification schemes (UNDER REVISION).
- [ISO/IEC 17026:2015](#): Example of a product certification scheme.
- [ISO/IEC 17007:2009](#): Guidelines for drafting normative documents suitable for use in conformity assessment schemes.
- [ISO/IEC TR 17032:2018](#): Guidelines and examples of a scheme for the certification of processes.
- [ISO/IEC 17050-1 & 2](#): Supplier's declaration of conformity (used in first-party schemes).





# Functional Approach (Core Concept)

All schemes, per ISO/IEC DIS 17067 ed.2, follow the **Functional Approach**:

- Selection → planning and sampling
- Determination → testing, auditing, inspection
- Review & Decision → evaluation of results
- Attestation → certification, declaration, accreditation

👉 This is the **backbone of conformity assessment**

# Objects of Conformity Assessment

A scheme must clearly define **what is being assessed**.

Possible objects:

- Product
- Service
- Process
- Management system
- Person
- Organization

# Examples Conformity Assessment Schemes (Global ACI Endorsed)

- The BRCGS Food Safety certification program
- Friend of the Sea scheme for sustainable practices in the marine industry
- The Food Safety System Certification (FSSC) 22000 scheme
- The International Civil Aviation Organization (ICAO), Carbon Offsetting and Reduction Scheme
- IPC Management System Auditors
- The PEFC Chain of Custody of Forest and Tree Based Products scheme

The logo for BRCGS (British Retail Consortium Global Standards) is displayed in orange, bold, sans-serif capital letters.

# Specified Requirements

Schemes must identify **what requirements must be met.**

Sources:

- Standards (ISO, ASTM, etc.)
- Regulations
- Technical specifications

Requirements must be:

- Clear and unambiguous
- Measurable or assessable
- Consistently applicable

👉 Poorly defined requirements = weak scheme



# Methodology of the Scheme

The scheme, per ISO/IEC DIS 17067 ed.2, defines **how conformity is demonstrated**.

Includes:

- Assessment methods (audit, test, inspection)
- Sequence of activities
- Decision rules
- Reporting format

Ensures:

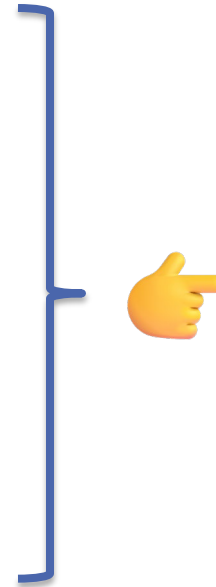
- Consistency across CABs
- Comparable results globally



# Core Elements of a Scheme

A robust scheme includes:

- Defined object
- Specified requirements
- Methodology
- Decision rules
- Surveillance mechanisms
- Governance structure



These elements collectively ensure:

- ✓ Credibility
- ✓ Reliability
- ✓ Market confidence

# Types of Schemes

Conformity assessment activities are categorized as:

- **First-party** → self-declaration
  - **Second-party** → customer-based
  - **Third-party** → independent certification/accreditation
- 👉 **Third-party schemes provide the highest level of trust**

# Role of the Scheme Owner

The Scheme Owner (SO) is central to the system  
*(IAF MD25, Criteria for the Evaluation of CAS)*

## Responsibilities:

- Develop the scheme
- Maintain and update it
- Authorize CABs
- Ensure consistency

## SO can be:

- Government
- Industry association
- Independent organization



# CABs and ABs, IAF MD25, Criteria for the Evaluation of CAS

Key actors:

## **CABs (Conformity Assessment Bodies):**

- Perform assessments

## **ABs (Accreditation Bodies):**

- Evaluate CAB competence

👉 Accreditation ensures:

- Impartiality
- Competence
- Consistency

# Global ACI MLA Structure

The **Global ACI** Multilateral Recognition Arrangement (MRA):

- Enables **global recognition of results**

Structured in levels:

- Level 1 is the endorsed normative document for ABs.(ISO/IEC 17011 )
- Levels 2 and 3 are the main scopes, consisting of accreditation programs and endorsed normative documents.
- Levels 4 and 5 are the sub-scopes consisting of applicable documents and endorsed normative documents, as noted above.

 **Ensures equivalence of outcomes worldwide**



# Global ACI MLA Structure (examples)

<b>Level 1</b>	<b>ISO/IEC 17011:2017</b>													
<b>Level 2</b>	Product Certification	<b>Management Systems Certification</b>										Person Certification	<b>Validation and Verification</b>	
<b>Level 3</b>	ISO/IEC 17065: 2012	<b>ISO/IEC 17021-1: 2015</b>										ISO/IEC 17024: 2012	ISO 14065: 2013,2020	ISO/IEC 17029: 2019
<b>Level 4</b>	GLOBAL G.A.P IFA General Regulations V4	ISO/TS 22003: 2013	ISO/TS 22003: 2013 FAMI-QS Rules for Certification Bodies Version 8	ISO/IEC 17021-3: 2017	ISO/IEC 17021-2: 2016	ISO/IEC 27006: 2015	ISO 50003: 2021	ISO/IECTS 17021-10: 2018	ISO/TS 22003: 2013 FSSC 22000 V5.1 Scheme Part 3	FSSC 22000 V5.1 Scheme Part 4	ICAO CORSIA ETM - Volume IV V1, ISO 14064-3:2019; ISO 14066: 2011			
<b>Level 5</b>	GLOBAL G.A.P. IFA Control Points and Compliance Criteria V4 (GLOBAL G.A.P.)	ISO 22000: 2018 (FSMS)	FAMI-QS Certification Scheme Code Version 6 (FAMI-QS)	ISO 9001: 2015 (QMS)	ISO 14001: 2015 (EMS)	ISO/IEC 27001: 2013 (ISMS)	ISO 13485: 2016 (MDQMS)	ISO 50001: 2018 (EnMS)	ISO 45001: 2018 (OH&S MS)	FSSC 22000 V5.1 Scheme Part 2 (FSSC 22000)	IPC- PL- 11- 006 (IPC)	ICAO CORSIA SARP's - Annex 16 Volume IV V1 (ICAO CORSIA)		



# Scheme Lifecycle

Schemes follow a structured lifecycle:

- Identify need
- Develop scheme
- Validate
- Implement
- Monitor
- Revise or withdraw

👉 Continuous improvement is essential



# Scheme Validation

Validation ensures the scheme is **fit for purpose**.

- Must demonstrate:
- Clear objectives
- Appropriate requirements
- Suitable methodology
- Justified conformity assessment approach

👉 Often includes pilot testing or benchmarking

# IAF MD 25 Evaluation

IAF MD 25 provides criteria for scheme evaluation.

ABs assess:

- Transparency of scheme
- Public availability
- Validation evidence
- Governance and impartiality
- Consistency across CABs

👉 Ensures schemes meet **international expectations**



# Risks of Poorly Designed Schemes

Weak schemes lead to:

- Inconsistent results
- Loss of credibility
- Regulatory rejection
- Market distrust

Key challenge

⚖️ Balance between:

- Flexibility
- Consistency

👉 Over-regulation reduces efficiency; under-regulation reduces trust



# Key Takeaways

- ✓ Schemes are the **core infrastructure of conformity assessment**
- ✓ They define **what, how, and why** conformity is assessed
- ✓ ISO/CASCO provides the global framework
- ✓ **Global ACI** ensures consistency and recognition

Strong schemes =

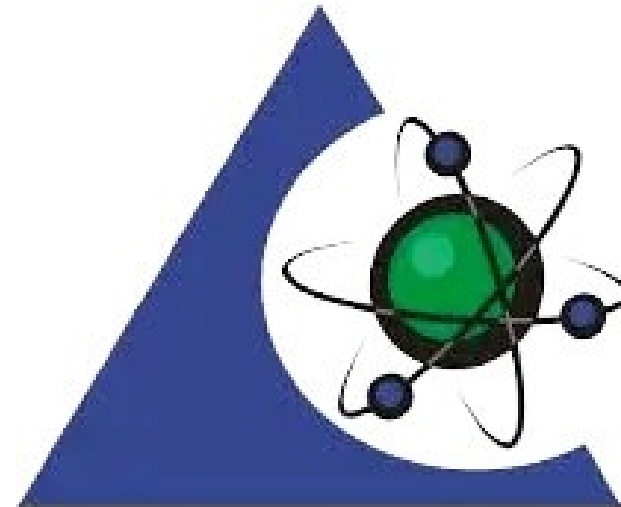
- Trust
- Market acceptance
- Consumer protection



# Thank You!

- Questions
- Discussion

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