



# Accredited and Adaptive: Unlocking the Power of Flexible Scopes

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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 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 is a Flexible Scope?

**ISO/IEC 17011:2017** defines a flexible scope as an expression *“to allow conformity assessment bodies to make changes in methodology and other parameters which fall within the competence of the CAB as confirmed by the accreditation body”*.

- **Result:** Allows CABs to introduce changes (items, analytes, parameters, methods) without prior AB approval.
- **Boundaries:** Changes must stay within defined competence and validated frameworks.
- **Comparison:** Fixed scope lists exact items/methods, flexible scope enables controlled autonomy.
- **Strategic importance:** Supports agility, responsiveness, and innovation in conformity assessment.



# Benefits for CABs

- **Faster response:** Introduce new services promptly to meet client needs.
- **Reduced delays:** Avoid constant reapplication for minor scope changes.
- **Encourages innovation:** Method development and continuous improvement encouraged.
- **Competitiveness:** Stay ahead in fast-changing industries and regulatory environments.
- **Efficient resources:** Broader technical coverage without duplication.
- **Strengthened credibility:** Demonstrates maturity and trust when well-documented.

# CAB Responsibilities

- **Shift of accountability:** AB transfers responsibility for scope changes to CAB.
- **Policies & procedures:** Must govern method development, validation, and verification.
- **Clear scope boundaries:** CAB must define what falls within flexibility and what doesn't.
- **Competence:** Only qualified personnel should authorize and validate changes.
- **Traceability:** Keep detailed records (who, what, when, how).
- **Oversight:** Flexible activities must be included in internal audits and management reviews.
- **Transparency:** Clients and ABs must be informed of activities performed under flexibility.

# References

- *PJLA Policy PL-4, rev1.9 - Scopes of Accreditation Policy*
- *ILAC-G18:12/2021 – Guideline for describing Scopes of Accreditation*
- *APAC TEC4-003, Guidance on Flexible Scopes of Accreditation*
- *EA-2/15, EA Requirements for the Accreditation of Flexible Scopes*
- *UKAS GEN4, Policy and general guidance for the implementation and management of flexible scopes of accreditation*



# PJLA Flex Codes (F0–F5)

**F0:** No flexibility – strictly fixed scope, no internal changes allowed.

**F1:** New item/material or adoption of latest revision of an unmodified standard method.

**F2:** Introduction of a new version of an accredited standard method (with no modifications)

**F3:** New analyte/parameter added to existing accredited method with validation.

**F4:** Modified non-standard method using same technology; requires validation and justification.

**F5:** Introduction of a new method that is equivalent to an accredited method (using same technology or technique).

**Flex Codes help clarify the extent of flexibility allowed for CABs  
under PJLA accreditation.**



# Practical Examples

- Testing lab: Validation of pesticide method for exotic fruit.
- Calibration lab: Calibration of a new thermometer brand not listed.
- Testing lab: Adoption of revised ISO method version.
- Chemical lab: Adding a new solvent to residual solvent testing suite.
- Calibration lab: Transition from manual to automated process.
- Medical lab: Extension of validated test from adults to pediatrics.
- Certification body: Extending QMS auditor certification to internal auditors.

# Example 1

Testing lab, accredited to ISO/IEC 17025, for pesticide analysis in vegetables receives an exotic fruit sample.

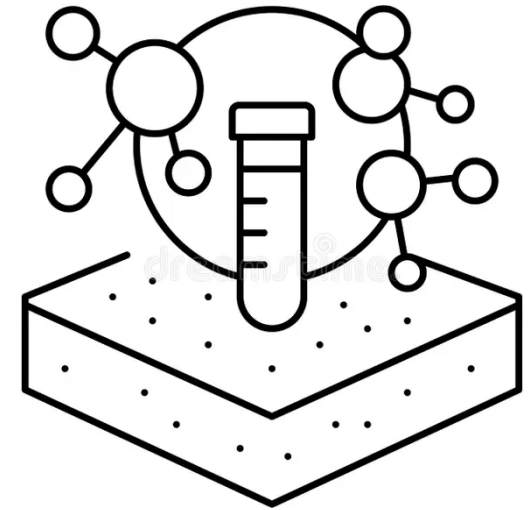
Under flexible scope (F1), the lab validates the method for the new matrix and performs accredited testing.



## Example 2

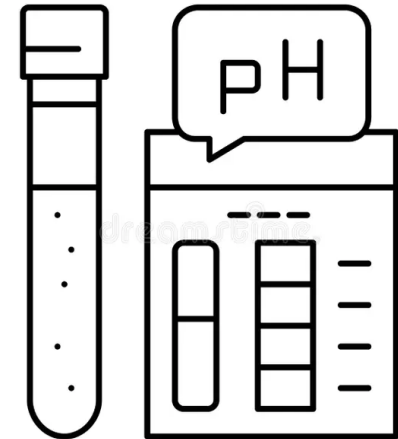
Testing lab uses ISO 7890-1:2015 for nitrate testing. Standard revised to ISO 7890-1:2023.

With F2, lab reviews changes, verifies equivalency, continues offering accredited results.



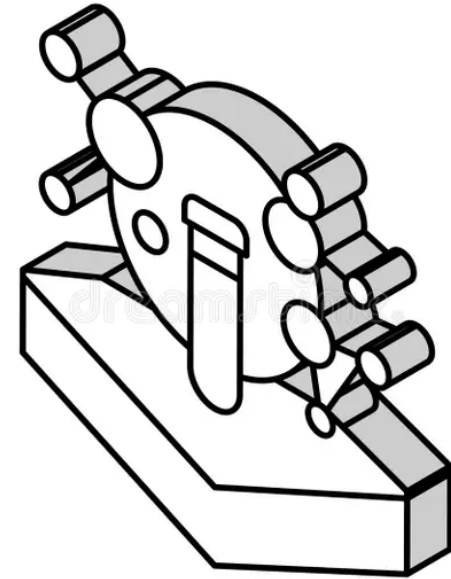
# Example 3

Chemical testing lab adds new solvent (e.g., acetone) to residual solvent suite. Under F3, it validates and records method extension internally.



# Example 4

Calibration lab accredited to ISO/IEC 17025 to calibrate digital thermometers. A new brand not listed is sent. With F1, same method applied after verification.

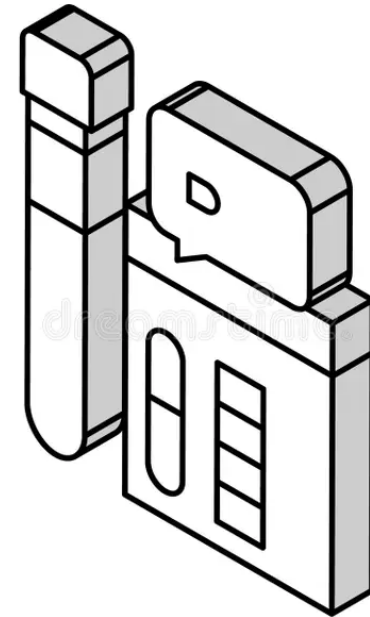




# Example 5

Calibration software upgrade.

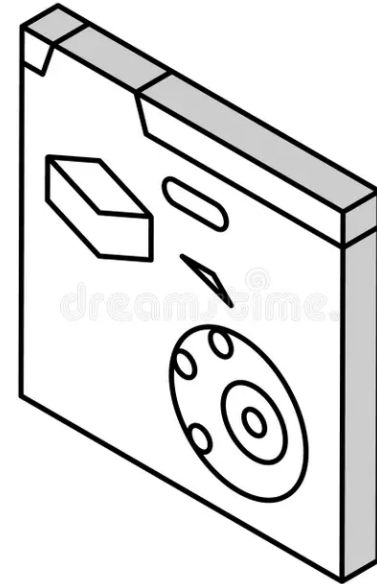
Under F2, lab documents new version's equivalence and continues accredited use.



# Example 6

Calibration lab replaces manual calibration with automated process using same standards.

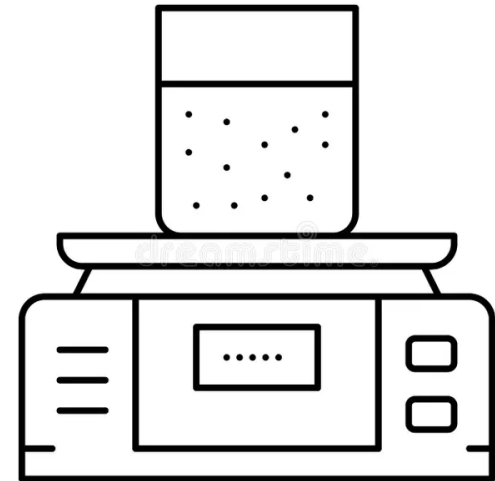
Under F5, documents method equivalency.



# Example 7

Medical laboratory accredited to ISO 15189, validated for adult patients, extends to pediatric use.

Verified under flexible scope, F3.



# Example 8

New biomarker introduced for cardiovascular screening using same platform.

Lab validates performance and offers it under flexible scope, F4.



## Example 9

ISO/IEC 17065 product CB updates scheme to latest version of referenced standard.

Reviews, confirms alignment, implements under flexibility, F2.



# Example 10

Inspection Body accredited to ISO/IEC 17020 inspects pressure vessels, adds a new vessel type of similar design.

Method adapted and verified internally under flexibility, F3.





# Example 11

Revised visual inspection checklist  
introduced for same item.

ISO/IEC 17020 Inspection Body reviews  
and implements under flexible scope, F5.



# Example 12

Reference Material Producer accredited to ISO 17034 produces standard solutions with a new solvent type. Mixture validated and issued under flexible scope, F4.



# Example 13

Personnel CB accredited to ISO/IEC  
17024 certifies Lead Auditors for QMS  
(ISO 9001).

Extends to Internal Auditors within same  
scheme under flexible scope, F3.



# Risks & Mitigation

- **Risk:** Unauthorized changes without validation →  
**Mitigation:** Enforce strict change control and documentation.
- **Risk:** Involvement of unqualified staff →  
**Mitigation:** Competence records, training, authorization protocols.
- **Risk:** Exceeding accredited scope boundaries →  
**Mitigation:** Strong review and awareness.
- **Risk:** Inadequate traceability/documentation →  
**Mitigation:** Templates, logs, clear change records.
- **Risk:** Poor client communication →  
**Mitigation:** Explicitly describe flexible activities in contracts and reports.

## **Reminder:**

**Flexibility is not less control; it requires more CAB maturity and robust systems**

# Conclusion

- Flexible scopes = agility + responsibility.
- They empower CABs to innovate and respond quickly while maintaining control.
- Accreditation Bodies view flexible scopes as higher-risk → more scrutiny on CAB's competence and systems.
- Success relies on robust validation, clear boundaries, competent staff, and transparent documentation.

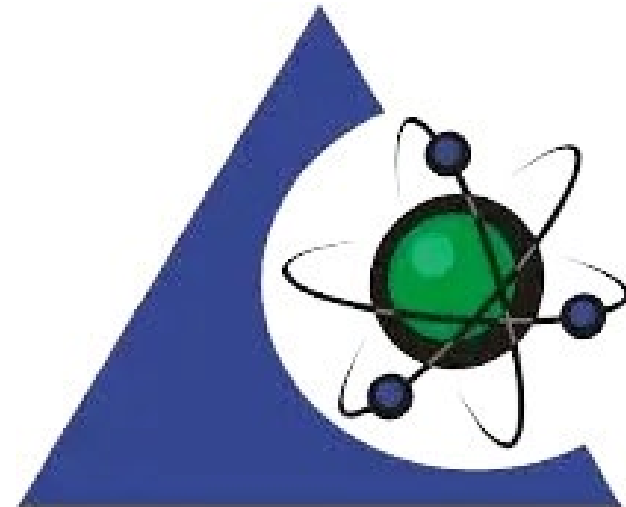
Final takeaway:

Flexibility is not about doing more, it's about doing more responsibly.

# Thank You!

- Questions
- Discussion

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