



Accredited and Adaptive: Unlocking the Power of Flexible Scopes

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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



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.

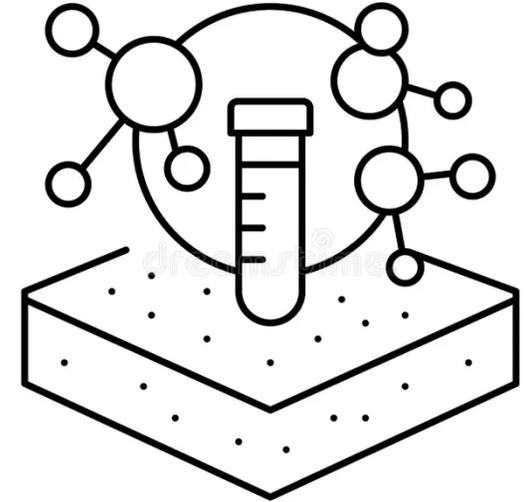
Under flexible scope (F1), the lab validates the method for the new matrix and performs accredited testing.



Example 2

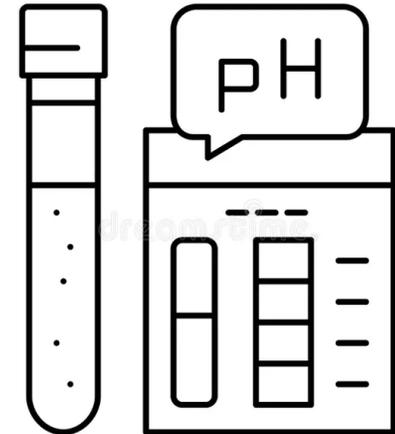
Testing lab uses ISO 7890-1:2015 for nitrate testing. Standard revised to ISO 7890-1:2023.

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



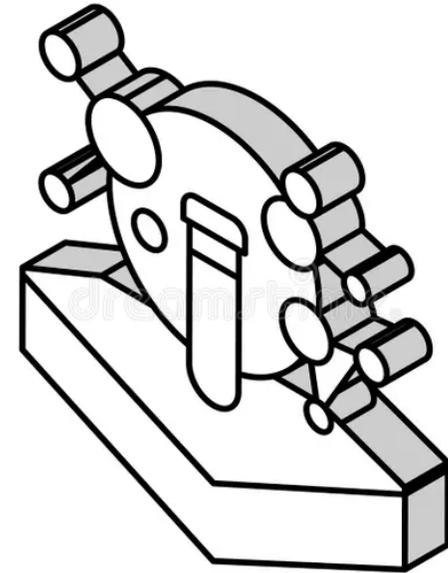
Example 3

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



Example 4

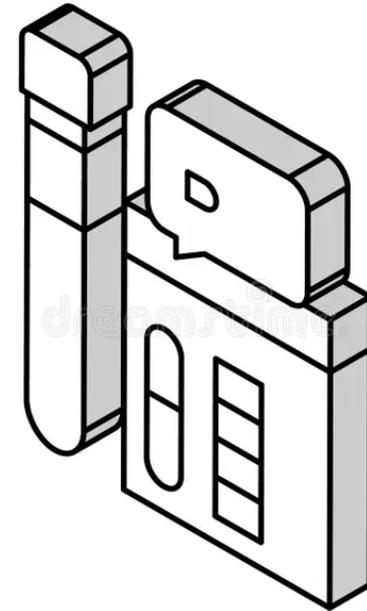
Calibration lab accredited to ISO/IEC 17025 to calibrate digital thermometers. A new brand not listed is sent. With F1, same method applied after verification.



Example 5

Calibration software upgrade.

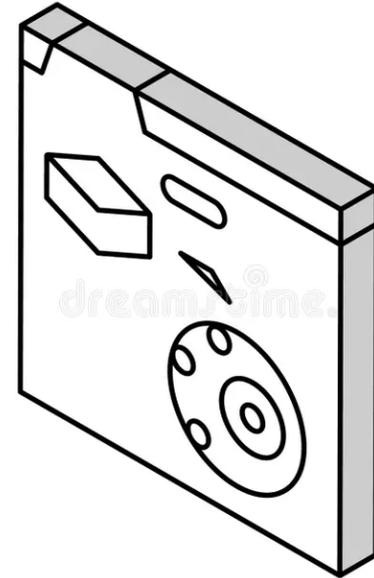
Under F2, lab documents new version's equivalence and continues accredited use.



Example 6

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

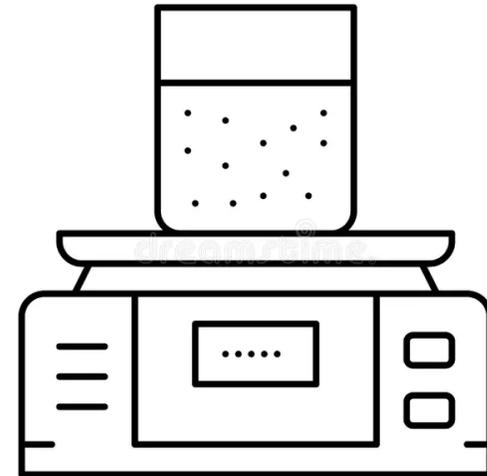
Under F5, documents method equivalency.



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:

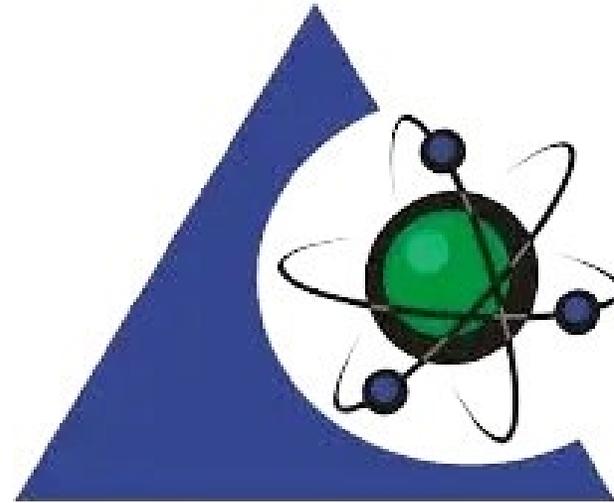
Flexibility is not about doing more, it's about doing more responsibly.



Thank You!

- Questions
- Discussion

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