Accredited and Adaptive: Unlocking the Power of Flexible Scope

By Dr. George Anastasopoulos*

Technical and Intl. Business Development Manager, PJLA

1. Introduction

Flexible scopes of accreditation allow Conformity Assessment Bodies (CABs) to operate with controlled autonomy in expanding or modifying their activities within defined parameters of competence. This article presents the key principles and usual Accreditation Bodies (AB) requirements to support CABs in understanding and implementing flexible scopes effectively. It emphasizes responsibilities, assessment considerations, and best practices for maintaining conformity with ISO/IEC 17000 series standards.

2. What is a Flexible Scope?

A flexible scope of accreditation allows a CAB to introduce changes—such as new items, analytes, parameters, or method versions—without prior approval from the AB, as long as these changes fall within defined bounds of competence and management control. It differs from a fixed scope, which lists specific items, methods, and parameters without allowance for internal changes.

3. Key Benefits of Flexible Scopes

Flexible scopes of accreditation provide CABs with a strategic advantage by allowing controlled changes—such as introducing new items, parameters, or method versions—without undergoing formal scope extensions. Key benefits include:

- Faster response to client needs: CABs can offer new or revised services promptly, improving customer satisfaction and turnaround times.
- Reduced administrative delays: Eliminates the need for formal applications and waiting for reassessment for every minor change.
- Support for innovation: Encourages continuous improvement and method development within validated frameworks.
- Increased competitiveness: Flexibility allows CABs to stay ahead in fast-moving sectors by addressing market demands quickly.
- Efficient use of resources: Staff and infrastructure can be optimized across broader technical coverage.

- Strengthened credibility: When properly documented and controlled, flexible scopes demonstrate technical maturity and trustworthiness to clients and regulators.

Ultimately, flexible scopes allow CABs to grow and adapt while upholding quality and compliance.

4. CAB Responsibilities under Flexible Scopes

Operating under a flexible scope of accreditation requires CABs to assume increased responsibility for ensuring that changes are controlled, validated, and fully documented. Unlike fixed scopes, flexibility shifts the accountability for implementing new or modified activities from the accreditation body to the CAB itself.

This means the CAB must have robust procedures in place to evaluate the suitability of changes, maintain competence, manage risk, and preserve the integrity of results. Transparency, traceability, and technical justification are critical, as assessors will evaluate not only outcomes but also how decisions were made and controlled.

CABs are expected to:

- Maintain documented policies for method development, validation, and verification.
- Define clear boundaries for flexible application within the scope.
- Ensure competence and authorization of personnel involved in flexible activities.
- Keep traceable records of changes introduced under flexibility (who, what, when, how).
- Include flexible activities in internal audits and management reviews.
- Inform clients and their AB when activities are performed under a flexible scope.
- CABs must demonstrate competence and risk management for new activities.
- Flexible scopes are subject to defined boundaries and must exclude entirely new principles or technologies.
- Quality systems must control all changes through validation, contract review, and internal oversight.
- Be assessed, occasionally, by ABs to verify audit flexible activities between scheduled visits.

5. Flexible Scopes Codes

Some ABs assign 'Flex Codes' to define the degree of flexibility permitted.

For example, PJLA's Flex Codes F1 to F5, are used to define levels of flexibility in the scopes of accreditation, initially introduced for testing and calibration laboratories, but also adapted for other CAB types.

These codes help ABs, CABs, and assessors determine the extent to which changes (e.g., to items tested, analytes, or methods used) can be made without prior approval, provided that internal controls, validation, and documentation are in place. In more details:

F0 = No Flexibility

The CAB must strictly follow the fixed scope. No changes are allowed to items, analytes, methods, or matrices without prior approval by the AB. Used when changes involve new technologies or unvalidated elements.

F2 = New Item, Material, Matrix, Product, or New Revision of Standard Method (Unmodified)

The CAB can test new items/materials/matrices that are similar in composition to those already accredited. Documented validation or verification is required to confirm method applicability to the new item.

The CAB may use the newest version of an already accredited standard method, as long as no modifications are made. Must confirm equivalence and document the review and implementation of the revision.

F3 = New Parameter/Analyte/Component

Introduction of a new analyte, parameter, or component into an already accredited test/certification method, when those specifics weren't initially listed on the scope. Must perform validation for the new addition and retain supporting documentation.

F4 = Modified Non-Standard Method (Same Technology)

Introduction of revised or modified internal (non-standard) methods that use the same technique or technology. Justification, validation, and internal approval are necessary. The change must not involve a new principle or drastically alter the method's identity.

F5 = Equivalent Validated Method

Use of a completely different but technically equivalent method, validated to achieve the same outcome using the same technology and for the same analyte or measurement. Full equivalency study, internal review, and documentation of method performance is expected by the AB.

6. Practical Examples of Flexible Scopes/Codes

The following examples illustrate how different types of CABs implement flexibility within defined boundaries, using various Flex Codes (F1–F5). These cases highlight the practical value of flexibility when backed by competence, validation, and documented control:

Example no1

A testing lab, accredited to ISO/IEC 17025, for pesticide analysis in vegetables receives a sample of an exotic fruit. Under flexible scope (F1), the lab validates the method for the new matrix and performs accredited testing.

Example no2

A testing lab, accredited to ISO/IEC 17025, uses ISO 7890-1:2015 for nitrate testing. The standard is revised to ISO 7890-1:2023. With F2 flexibility, the lab reviews changes, verifies equivalency, and continues offering results as accredited.

Example no3

A chemical testing lab, accredited to ISO/IEC 17025, adds a new solvent (e.g., acetone) to its residual solvent testing suite. Under F3, it performs validation and records the method extension internally.

Example no4

A calibration lab is accredited to ISO/IEC 17025 to calibrate digital thermometers. A client sends a new brand not listed. With F1 flexibility, the lab uses the same method and calibrates under scope after internal verification.

Example no5

Calibration software, used by a lab accredited to ISO/IEC 17025, receives an upgrade. Under F2 flexibility, the lab documents the new version’s equivalence and continues its use.

Example no6

A calibration lab, accredited to ISO/IEC 17025, replaces manual calibration with an automated process that uses the same standards. Under F5, the lab documents method equivalency and applies it under accreditation.

Example no7

A medical laboratory accredited to ISO 15189, for adult patients, is validated for pediatric use. Under flexible scope, the lab performs verification and adds the patient group.

Example no8

A new biomarker is introduced for cardiovascular screening using the same platform. The lab validates performance and offers it under its flexible scope.

Example no9

An ISO/IEC 17021 accredited CB for ISO 9001 in the field IAF 18 (basic metals) wishes to certify in fabricated metal products. With documented competence and flexible scope, they certify without applying for an extension.

Example no10

An ISO/IEC 17065 accredited product certification body needs to update its scheme to the latest version of one of the referenced standards. The CB reviews the revision, confirms alignment, and implements it under flexibility.

Example no11

An Inspection Body accredited to ISO/IEC 17020 to inspect pressure vessels, adds a new vessel type of similar design/materials. Under flexible scope, the inspection method is adapted and verified internally.

Example no12

A revised visual inspection checklist is introduced for the same item. The, ISO/IEC 17020 accredited, Inspection Body reviews and implements it under an approved flexible scope.

Example no13

A Reference Material Producer accredited to ISO 17034 produces standard solutions with a new solvent type for which competence has already been demonstrated. The mixture is validated and issued under the flexible scope.

Example no14

A personnel certification body is accredited to ISO/IEC 17024 to certify "Lead Auditors for Quality Management Systems (QMS)" under ISO 9001. They receive a request to certify “Internal Auditors” for QMS within the same technical scheme. The scope is extended, under flexible scopes, since the activity is within the same occupational category (QMS auditing), uses the same normative standard (ISO 9001), and relies on an existing, validated evaluation methodology.

7. Assessment Focus Areas

When evaluating flexible scopes, ABs focus not only on technical competence but also on the systems used to manage flexibility. AB assessors will review how the CAB identifies,

documents, validates, and implements changes within its accredited boundaries. Key assessment elements include:

- Validation and verification records for new or modified items, methods, or matrices.
- Evidence of contract review that considers whether activities fall within the approved scope.
- Competence records confirming that only authorized, qualified personnel are making technical decisions related to flexibility.
- Change control procedures, demonstrating that modifications are systematically approved, documented, and traceable.
- Management system integration, ensuring flexible activities are subject to internal audits and management review.

AB assessors may request specific examples of flexibility being applied and examine the traceability of decisions. Ultimately, the goal is to confirm that flexibility enhances responsiveness without compromising compliance or quality.

8. Risks and Mitigation Measures

Operating under a flexible scope introduces several operational and compliance risks that must be managed by the CAB through a robust quality system.

A key risk is the unauthorized implementation of new or modified methods without proper validation. To mitigate this, CABs must enforce strict change control procedures, maintain validation records, and clearly define internal approval authority.

Another common risk is the use of unqualified or unauthorized personnel in decision-making related to flexibility. This can be addressed by documenting competence requirements, ensuring relevant training, and maintaining up-to-date competence records.

There is also the danger of exceeding the boundaries of the accredited scope, especially when introducing new analytes, matrices, standards or technologies. Effective contract review, scope awareness, and periodic internal reviews are essential to ensure compliance.

Inadequate documentation or the traceability of flexible activities poses both operational and assessment risks. Standardized templates and detailed logs of each change—who performed it, what was changed, and how it was validated—are critical.

Lastly, poor communication with clients regarding flexible activities can lead to misunderstanding or loss of trust. CABs must ensure that all accredited services delivered under flexibility are clearly described and justified.

9. Conclusion

Flexible scopes of accreditation offer CABs the ability to adapt to market needs more efficiently, allowing them to introduce new items, methods, or revisions without prior AB approval—provided these remain within clearly defined boundaries of competence.

However, flexibility is not a relaxation of requirements. It places greater responsibility on the CAB to maintain robust internal controls, demonstrate technical competence, validate changes, and retain traceable records. ABs assess not only technical outputs, but the systems that govern change.

For ABs, a request for flexible scope is not simply a procedural variation — it's a signal for heightened vigilance. While flexibility empowers CABs to adapt swiftly, it also transfers significant decision-making authority from the AB to the CAB. This shift raises concerns about whether the CAB has maturity, competence, and systems in place to manage this responsibility responsibly.

In practice, a flexible scope means the CAB may introduce new items, analytes, or method revisions without prior review. For the AB, this triggers a "ringing bell" — an internal alert that risk has moved upstream, and deeper scrutiny is required. ABs assessors are trained in such situations to go beyond technical results and investigate how changes were approved, who validated them, and what controls were applied.

When properly managed, flexible scopes enhance responsiveness, reduce delays in service delivery, and support innovation—while preserving confidence in the accreditation process. The success of this model relies on clear documentation, competent personnel, and an effective quality system.

Ultimately, flexible scopes are not about doing more, they are about doing more with control. Properly applied, they deliver agility without compromising integrity.

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About the author

Dr. George Anastasopoulos is the Technical and International Business Development Manager of Michigan, USA, based Perry Johnson Laboratory Accreditation Inc. (PJLA), a globally recognized third-party accreditation body involved in technical and scientific conformity assessment activities in multiple industrial sectors. He is also the General Secretary of the International Personnel Certification Association (IPC).

He is a Mechanical Engineer with an MSc and a PhD in Applied Mechanics from Northwestern University, Evanston, Illinois. He is also a member of a series of technical committees such as ISO/TMBG, ASTM, IPC, ISO/TC176 and ISO/CASCO and he is also actively participating in global accreditation IAF and ILAC meetings.

Dr. George Anastasopoulos is awarded with the EOQ Presidential Georges Borel Award for international achievements being at the edge of the development, use and diffusion of quality at international level through his professional activities and behaviors, personally contributing to the development of the European Quality movement through his accomplishments with a global impact in the field of quality.

Dr. Anastasopoulos presented many papers in technical and financial conferences, magazines and newspapers and is the author of many articles and books. He is also a reviewer for Scientific Journals. Dr. Anastasopoulos presented many lectures as keynote speaker in topics such as Conformity Assessment, Management Systems, Business Process Reengineering, Telecoms-FTTH-IT, Quality Assurance and Process Auditing. He participated in numerous consulting and research projects sponsored by government and industry in the USA, European Union and many other countries worldwide.

Dr. Anastasopoulos can be reached at: ganast@pjlabs.com