

UKAS Approach to Flexible Scope EPPO Meeting - 9th-11th September 2019

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What can be included in a Flexible Scope?

Flexible scopes have been used by laboratories for:

- inclusion of new methods in accordance with a generic protocol
- modification of existing methods to broaden their applicability (*e.g. to deal with new matrices or determinands, etc.*)
- inclusion of newly revised or technically equivalent standard methods or specifications that are already covered by accreditation
- inclusion of new (temporary) site laboratories

Benefits of Flexible Scope

- Recognise laboratories with wider breath and depth of competency than covered by fixed scope of accreditation
- Fixed scopes does not enable additional/modified activities without further assessment
- UKAS can not always respond to laboratory's timescale to meet their client requirements
- Can reduce unnecessary work to progress a simple extension to scope (ETS)

Flexible Scope on schedules

- The flexible scope schedule entry states the following to define this activity:
 - The matrix
 - The test parameter eg diagnosis of plant pathogens and pests
 - The flexible scope procedure reference
 - The technique eg RT-PCR

Boundaries of Flexible Scope

The bounds within which the scope is flexible must be clearly defined, with the laboratory demonstrating to UKAS that it has the knowledge, experience and competence to work within the full range of its flexible scope

- the materials/products tested - matrix
- properties measured - determinands
- equipment/techniques used

Who decides on the Flexible Scope?

Laboratory to:

- determine what its requirements are
- work out how it can be achieved
- demonstrate approach is fit for purpose and can be controlled

Accreditation Body decides:

- whether to offer service
- how to define scopes
- whether or not to grant flexible scope

Flexible Scope Reference

- **EA-2/15 M:** EA Requirements for the Accreditation of Flexible Scopes (July 2008 , April 2019)
- **UKAS LAB 39:** UKAS Guidance on the Implementation and Management of Flexible Scopes of Accreditation within Laboratories (August 2004)
- **UKAS TPS 59:** Implementation and Management of Flexible Scopes of Accreditation for the Commissioning of Site Laboratories (November 2013)
- **GEN 4** - To be published in 2019
- Provides amplification and guidance on the current requirements within the international standard

Requirements on laboratories

- List of activities conducted under flexible scope, available on request
- Documented system covering:
 - Resources/competence
 - Assigned responsibilities
 - Validation/verification
 - Approvals and authorisations
 - Premises
 - Contract review
- Analysis and consequences of validation failures

Requirements on UKAS

- Procedures for offering flexible scopes (LAB 3, GEN 4)
- Verification of competence of laboratory to manage a flexible scope
- Reference to list of activities on schedule (reference procedure, list of techniques etc)
- Dealing with end-user enquiries
- Sanctions where appropriate

Concerns on expanding Flexible Scopes

- Maintaining methodology infrequently used
- Competence evidence on an on-going basis
- Demonstrating infrequent fixed scope testing is already an issue (TPS 68)
- Understanding of flexible scope and how to use it is more complex than a fixed scope!

Thank you for listening

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