

Use of flexible scopes in the Netherlands

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Use of flexible scopes

- Documents
- Conditions/ Allocation
- Scope description
- Difference fixed and flexible scope



Documents

- ILAC G18, Guideline for the Formulation of Scopes of Accreditation for Laboratories
- EA-2/15 M EA Requirements for the accreditation of flexibel scopes
- RvA- T025 “Scopes of Testing Laboratories”
 - Explanatory document
 - T-documents are mandatory
 - Describes the procedure of the RvA regarding scopes of testing laboratories



Conditions for flexible scope

The laboratory has a demonstrated expertise in the area of tests to be accredited and/or during previous assessments has demonstrated that it has implemented new and/or revised tests correctly.



Allocation of flexible scope

- Application for extension on the basis of a detailed practical example
- Procedure
- Competence; tasks and responsibilities
- Validations
- Project documentation
- Internal audit and decision making
- Reports



Scope

- Separate heading
- Footnote on scope:

"Under this flexible scope, a laboratory is obliged to maintain an up-to-date list of the methods that are carried out under this flexible scope. "



Example

Material or product	Type of activity	Internal reference number
Flexible scope^x		
Plant material	Determination of plant viruses and viroids using bioassay (using test plants); DAS-ELISA, PCR, Real-time PCR, PCR-Sequencing	R-XXX

* Under this flexible scope, a laboratory is obliged to maintain an up-to-date list of the methods that are carried out under this flexible scope

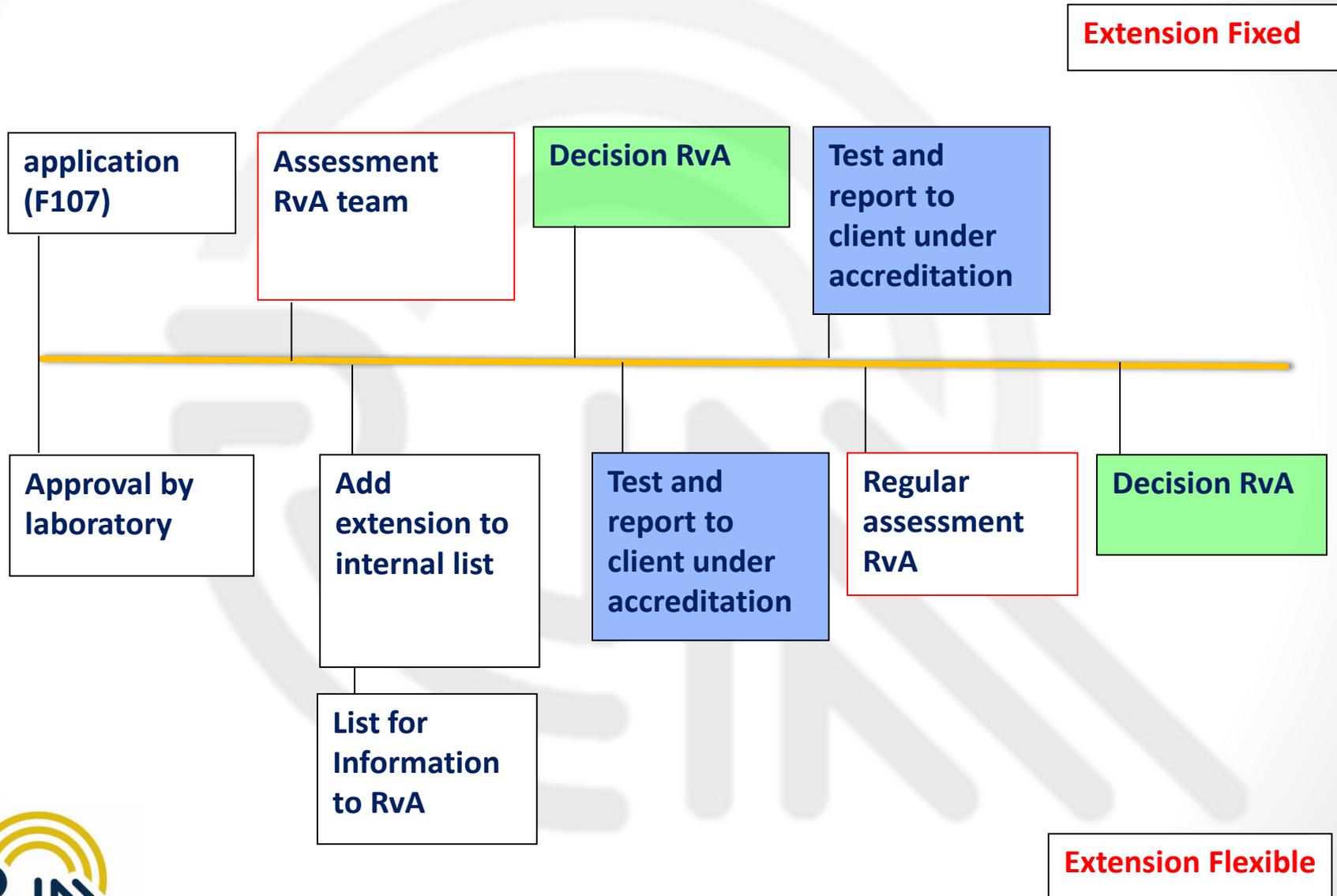


Difference fixed- flexible

- Fixed
Report under accreditation after assessment by RvA
- Flexible
Report under accreditation before assessment by RvA



Difference fixed- flexible



Consequences flex

- discrepancies found with regard to validation within the (flexible) scope:
 - clients involved have to be notified
 - corrective actions for all areas where the non-conformity could have an impact
 - reports might need to be recalled



Conclusion

- Difference between fixed and flexible scope
- Flexible scope is possible if the laboratory has a demonstrated expertise in the area of tests and has implemented new and/or revised tests correctly



