

Annex 8.7 Evaluation criteria laboratory performance assessment

Determination of an individual test result

The following requirements must be fulfilled to pass an individual laboratory performance assessment:

- all parameters (analytes) detected
- at least n-X analytes correctly quantified. X varies according to the number of parameters (analytes) to be analysed between 0 and 3
 - (The |z-score| for every analyt must be ≤ 2 .)
- · No false positive analytes found.

If the laboratory performance assessment is not passed, it is mandatory to participate in another external proficiency test within six months after completion of the laboratory performance assessment. If this ring test is not passed either, the laboratory loses the QS approval for the corresponding parameter.

If <u>three consecutive laboratory performance assessments</u> are not passed, the laboratory loses its QS approval.

After <u>losing the approval for a parameter</u>, it can only be recovered after six months at the earliest

The condition for recovering the approval is:

- successful participation in at least another external ring test
- · new revision of the documents by QS

After <u>losing the complete QS approval for a laboratory</u>, it can only be recovered after six months at the earliest.

The conditions for recovering the approval is:

- successful participation in a QS laboratory performance assessment. If this is not possible because there is not a laboratory performance assessment being offered, it is possible to prove the participation in a comparable external proficiency test.
- succesful document revision by QS
- successful laboratory audit at owner's expense