

Protocol for management of underperformance in comparative testings or lack of collaboration of NRLs

According to EU Regulation EC/882/2004, the organization and follow up of comparative testing of National Reference Laboratories is a key responsibility for European Union Reference Laboratories. That same regulation states the commitment of collaboration of NRLs with the corresponding designated EURLs.

In order to ensure an appropriate follow up in case of underperformance or lack of collaboration of NRLs, the next two step procedure for EURL actions shall be applied.

In case of underperformance (e.g. proficiency tests):

PHASE 1

1. After publication of the test report (even in working document version), the EURL shall contact the underperforming NRL asking to report on the possible causes of the observed deviations.
2. NRL response shall be transmitted by email to the EURL within 10 working days after request for information.
3. Upon acknowledgment of reception of the explanation, the EURL shall decide if the case can be closed or if further corrective actions need to be taken. Decision will be notified to the NRL. During this first step, strict confidentiality will be kept.
4. In case further action is needed (i.e. repetition of test, on-site visit or training), the EURL shall inform the NRL which action will be decided. After corrective action, a re-assessment of the NRL shall be realised and notified to the NRL.
5. In case of on-site remediation, a dedicated mission report form shall be written by the EURL including, if needed, a “to do” list as well as due dates for the “to do” items. This report shall be transmitted to the NRL as well as to the Commission (for information only). The NRL shall inform the EURL on due dates on the achievement of the “to do” items.

In case of repeated underperformance, or if corrective actions from PHASE 1 still result in an underperforming situation, or if the NRL does not fully collaborate to solve the PHASE 1 requirements, PHASE 2 will be initiated.

PHASE 2

6. The EURL will officially inform the Commission and transmit the dossier to DG SANTE. The Commission shall inform the competent authority of the Member State and require that appropriate actions are taken.

In case of lack of collaboration (e.g. no participation to a workshop)

PHASE 1

1. The EURL shall contact the NRL asking to report on the lack of collaboration.
2. The NRL response shall be transmitted by email to the EURL within 10 working days after request for information.
3. Upon acknowledgment of reception of NRL response, the EURL shall decide if the delivered explanation is justifying the lack of collaboration. The justification of the NRL shall be transmitted to Commission for information.

In case of repetitiveness of lack of collaboration, or in case of absence of response by the NRL, PHASE 2 will be initiated

PHASE 2

4. The EURL will officially inform the Commission on the situation. The Commission shall inform the Competent Authority of the Member State and require that appropriate actions are taken.

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