NQAAP pilot EQA programme support mechanism

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1. Introduction and purpose

As new methods and clinical tests are introduced into healthcare the development of new external quality assessment (EQA) programmes is of critical importance to support patient safety. Ideally, EQA should be in place before new methods/clinical tests are introduced, however it is acknowledged that this may not always be possible.

2. Scope

This document is available to all stakeholders and outlines the roles and responsibilities of groups in the development of new EQA programmes.

3. Procedures for pilot EQA development mechanism

3.1 The role of EQA providers in the development

As per ISO 17043 4.4.1.2 Conformity assessment – General requirements for proficiency testing, “The proficiency testing provider shall not subcontract the planning of the proficiency testing scheme.” **Note:** The proficiency testing provider can utilise advice or assistance from any advisors, experts or steering groups.

Therefore, sole responsibility for the planning and introduction of a pilot EQA programme rests with the individual EQA provider.

It is expected that EQA providers will be aware of the need for EQA in their area of expertise and will develop programmes according to their established practices. However, input in terms of EQA need and importance can be made by any group or individual interested party (e.g. a clinical laboratory or commercial manufacturer). Such input should then be assessed by the EQA provider as per their normal procedures.

The implementation of a pilot EQA programme depends on multiple factors, including (but not limited to) material availability, clinical priority, sufficient laboratories for EQA operation, appropriate funding, workload implications and access to relevant expertise. As such even when there is a recognised need, it is not always possible to implement EQA.

When developing any pilot EQA programme it is expected that EQA providers will consult with stakeholders before implementation. This consultation can include dialogue with participating laboratories, with steering committees and specialist advisory groups and liaison with the appropriate National Quality Assurance Advisory Panels (NQAAPs). Such consultations would be undertaken as required by the EQA provider and may vary in terms of groups approached, topics covered and nature of advice/consultation required.

Once an EQA provider has decided to establish a pilot EQA programme (irrespective of the route of initial identification of need), they should notify the relevant NQAAP chair. At a minimum this should be done as part of their annual report.

3.2 The role of the NQAAP and QAPC in the development of pilot EQA programmes

The role of these groups is twofold:

a. to highlight to EQA providers any areas/gaps/new technologies that will require EQA provision.

   Where members of an NQAAP or the QAPC are aware of a gap in EQA provision they should raise this simultaneously with the EQA providers working in that area (as defined by those that attend the relevant specialty NQAAP). This is easiest to achieve during an NQAAP meeting, however the chair of the NQAAP/QAPC may decide to raise the issue sooner via an alternative route.

b. to provide support (where requested) to EQA providers in developing EQA programmes.

   Where an EQA provider requires support in development of a pilot EQA programme, they should contact the chair of the relevant NQAAP directly with their request. The support available (where possible and practicable) would be facilitating introductions to relevant advisors (clinical or scientific). To avoid any potential conflicts of interest, members of the NQAAP will not undertake the role of advisor for any EQA programme. Under the funding mechanism for the operation of the NQAAPs there is no provision for financial support to EQA providers for pilot programmes and as such support in this area is not possible.

During the initial exercises of pilot EQA programmes, performance monitoring is often not undertaken or is for information purposes only. However, it is realised that there may be genuine performance issues identified in this period. In such situations, the NQAAP may be made aware of issues relating to laboratories in pilot EQA programmes as part of routine operations if an issue is identified with sufficient confidence by the EQA provider. In these cases, any identified issue of performance (however termed by pilot EQA programme providers) would be viewed as of equal significance to those seen in established EQA programmes and dealt with following the same processes by the relevant NQAAP.

The EQA provider should outline to the NQAAP their intentions and timelines for accreditation of the EQA programme at the pilot stage. Where performance issues are identified or where there is an urgent clinical laboratory need, the relevant accreditation body should be contacted at the earliest opportunity to assess the pilot and include it in its scope of accreditation.