Process for uniquely identifying a laboratory to NQAAPs

Title	Process for uniquely identifying a laboratory to NQAAPs
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1. Introduction and purpose

The following general guidance was produced for general operation of National Quality Assurance Advisory Panels (NQAAPs) and is intended for NQAAP members, Quality Assurance in Pathology Committee (QAPC) members and external quality assessment (EQA) providers reporting UK performance to NQAAPs.

In accordance with ISO17043 the identity of any participants in an EQA scheme is confidential. However, confidentiality can be waived for regulatory purposes.

This policy describes how confidentiality will be waived when reporting performance of UK clinical laboratories into the NQAAPs and QAPC assurance framework.

2. Responsibilities

EQA providers are responsible for identifying laboratories to the NQAAP/QAPC. Members of the NQAAP/QAPC are responsible for ensuring the secure and confidential storage of any identifiable information.

3. Procedures

3.1 For EQA providers

As the operators of the EQA schemes and holders of confidential data, the initial waiving of confidentiality will be done by EQA providers in response to performance concerns that could affect patient safety or have therapeutic implications. For example, a positive COVID-19 test may not affect safety but could have implications for what treatment (e.g. chemotherapy) would be chosen.

Participants in any EQA scheme must be informed of arrangements where confidentiality with the EQA provider will not apply in advance of participation. To ensure clarity and avoid confusion all EQA schemes reporting into the EQA Governance and Assurance Framework should use the following statement in their terms and conditions of participation for all UK laboratories.

3.1.1 Statement to be provided to UK clinical laboratories enrolled in EQA

The EQA schemes operated by {EQA Provider Name} participate in the United Kingdom EQA Governance and Assurance Framework. This framework is a collaboration between EQA providers, the Royal College of Pathologists (RCPath), professional bodies and regulatory organisations. As part of this framework any issues of persistent poor performance (PPP) identified in UK clinical laboratories will be reported to the relevant NQAAPs for the benefit of patient safety. As per the NQAAP terms of reference (document WS10904) a holistic approach to responding to PPP will be undertaken to ensure cross system performance is monitored. This will be achieved by requesting any laboratories that are identified to provide details to the NQAAP of their EQA performance in other areas and this will be shared with other NQAAPs and QAPC as appropriate.

Reporting of performance issues will involve disclosure to the relevant NQAAP of your head of department, laboratory name, address and healthcare organisation, together with methodological and EQA performance information. Any details provided to the NQAAP will be securely shared with other NQAAPs and the QAPC.

3.1.2 Process

No performance information will be shared with other EQA providers reporting to the same NQAAP and should be provided to the relevant NQAAP chair in line with the timelines of the Escalation policy (document WS20501) as an incident of PPP and within the EQA scheme's annual report as part of a closed session.

When identifying a laboratory to the NQAAP the EQA provider should submit the following details:

- date issue identified
- head of laboratory
- laboratory name
- laboratory address
- healthcare organisation.

3.2 For NQAAPs and QAPC

When confidential data regarding the identification of a laboratory and associated performance issues is made it is shared in the first instance with the relevant NQAAP chair and associated members. This information remains confidential and should not be shared outside of the EQA Governance and Assurance Framework.

The chair of the relevant NQAAP is responsible for sharing the laboratory identification details with chairs of other NQAAPs and the QAPC. This ensures that any other performance issues at same the laboratory/site/healthcare organisation are considered as part of a comprehensive overall process rather than in isolation.

3.2.1 Confidentiality

All information provided to the QAPC and NQAAPs by EQA providers will be classed as confidential. To ensure confidentiality is maintained:

- any information provided should not be distributed outside of the NQAAP/QAPC framework
- all documentation should be password protected when circulated electronically to NQAAPs/QAPC members
- secure email facilities (such as NHS mail) should be used where possible
- all confidential information should be returned (hardcopies) or destroyed (hardcopies and electronic data) on ceasing to be a panel member.

These points are supplementary to local confidentiality procedures/practices in place for panel members and do not replace established local practices or national guidance.

Any breaches of confidentiality will be investigated under the dispute resolution policy with appropriate corrective and preventative measures implemented to prevent a recurrence.

4. Related documents

Dispute resolution policy (document WS10223)

Escalation policy (document WS20501)

NQAAP terms of reference (document WS10904)