Escalation of EQA performance concerns policy

Title	Escalation of EQA performance concerns policy
Policy number	WS20501
Authors	EQA Quality Improvement Workstream 2, Dr Barbara De la Salle, Dr Ros Hastings, Andy Dodson, Dina Patel and Alan Young
Version	1
Approved by	EQA Oversight Board
Issued date	September 2023
Review date	September 2028

Contents

1. Introduction and purpose

This document provides a policy and template for the escalation of performance concerns in external quality assessment (EQA) by UK diagnostic laboratories and testing sites to the National Quality Assurance Advisory Panels (NQAAPs), the Quality Assurance in Pathology Committee (QAPC) and the Care Quality Commission (CQC) or equivalent across the devolved nations.

The pathway for escalation of performance concerns is from the EQA organiser to the discipline specific NQAAP, from the NQAAP to the QAPC and then from the QAPC to the Medicines and Healthcare products Regulatory Agency (MHRA) or the equivalent bodies across the devolved nations (see document WS20502). The timely escalation of performance concerns, regardless of the EQA provider and NQAAP discipline, is essential for the effective management of persistent poor performance (PPP) in diagnostic testing and the timely response to associated threats to patient safety.

It is recognised that healthcare staff operate in complex systems, with many factors influencing the likelihood of error. These factors include medical device design, volume of tasks, clarity of guidelines and policies, and behaviour of others. The EQA Governance Collaborative supports a ‘systems’ approach to error, which considers all relevant factors and focuses on strategies that maximise the frequency of things going right in a just culture.

It is also recognised that the system should share details of the performance of clinical laboratories with patients and the public. The EQA Governance Collaborative recognises the importance of this and will work towards this. Currently, the detail of performance concerns remains confidential throughout the process, but the anonymity of the laboratory is removed at the point at which a referral is made to the NQAAP for performance concerns. The removal of anonymity is included in the Terms and conditions of participation of the EQA provider (document WS10904) and is supported by the QAPC. The process for identification of a laboratory to the NQAAP is described in the Process for uniquely identifying a laboratory to NQAAPs (document WS10201).

2. Scope

The pathways describe the oversight of the performance of diagnostic laboratories and other testing sites in the UK. The documents may be used to report to oversight bodies in other regions or countries where these exist and where the EQA organiser has an agreement to report performance concerns.

3. Tools

3.1 Flowchart (document WS20502)

The flowchart describes the process and expected timeframes for escalation and review of EQA performance concerns. Note that the flowchart indicates interactions between aspects of the EQA Governance Collaborative and this is not to be a strictly linear process.

3.2 Template for escalation of PPP concerns (document WS20503)

This template is based on the Situation, Background, Actions, Response (SBAR) form for each phase of escalation.

The template comprises the following sections:

- laboratory details
- EQA provider details
- EQA provider's report
- NQAAP report
- QAPC report
- report to regulatory bodies or equivalent across the devolved nations
- outcome and lookback review
- closure date and signature
- list of attachments.

Not all stages of escalation will be required in all cases of PPP investigation and the stages used will depend on the clinical significance of the PPP and its potential impact on patient safety.

4. Responsibilities

4.1 Service commissioners

Commissioners of diagnostic testing services should ensure that the providers of services are accredited to ISO 15189 Medical laboratories – Requirements for quality and competence.

4.2 EQA participant

The EQA participant should ensure that the chosen EQA provider is accredited to ISO/IEC 17043 Conformity assessment – General requirements for proficiency testing. The diagnostic testing provider should ensure that the EQA provider is a member of the EQA Governance Collaborative and reports to the relevant discipline specific NQAAP.

The EQA participant should disclose actions taken in response to a patient safety event (PSE) and/or PPP to the EQA provider and the relevant NQAAP when requested. This should include actions taken to mitigate any associated threats to patient safety. Where a UKAS-accredited diagnostic testing provider is referred to the NQAAP for PPP, they should provide their UKAS accreditation number to the NQAAP when requested.

Where the EQA participant subcontracts testing to another provider, they should ensure that the subcontractor operates to the same standards of oversight as their own services, regardless of where the subcontractor is based.

4.3 EQA provider

The EQA provider should establish performance standards that comply with the definitions described in the Error and poor performance policy (document WS20301) and for making these available to their participants.

The EQA provider should ensure that UK participants are aware of the circumstances in which the participant's identity will be disclosed to the NQAAP.

The EQA provider should ensure the timely monitoring and notification of performance concerns to the participant. Where appropriate, the EQA provider should supply support to assist the participant to resolve performance concerns. The EQA provider should ensure that the performance of the participant and any correspondence about poor performance is recorded and is available to the oversight body if required.

The EQA provider should have a process by which the participant is made aware that their performance may result in escalation to the NQAAP, including disclosure of their identity, prior to referral to the NQAAP. This process may be included in standard notification letter text, included in terms and conditions, or notified on each occasion, as appropriate to the scheme design and operation.

The EQA provider should disclose the identity of the laboratory to the NQAAP chair at the time that the laboratory is referred for PPP, as described in the Process for uniquely identifying a laboratory to NQAAPs (document WS10201).

The EQA provider should monitor possible scheme hopping and report this to the NQAAP, as described in the Scheme hopping policy (document WS20313).

4.4 Chairs and members of oversight bodies (NQAAPs, QAPC, CQC)

The chairs and members of the NQAAPs should be familiar with the various performance standards of the individual EQA providers reporting to them.

The chairs and members of each oversight body should ensure that the records of performance escalated to them are maintained securely and in confidence. They should ensure the confidential disposal of the records at the stated time interval as described in the Process for uniquely identifying a laboratory to NQAAPs (document WS10201).

The chair and members are responsible for contacting the poorly performing laboratories and suggesting a written course of action once the necessary documentation has been received.

5. Procedures

The escalation pathway and timescales are shown in the escalation flowchart (document WS20502).

Notification may be made by post, courier or email. If email is used, messages should be fully encrypted, e.g. between nhs.net email accounts.

5.1 Reporting PSEs and/or performance concerns to the NQAAP

The EQA provider should either notify the participant that they are to be referred to the NQAAP chair, with the reasons, or should have a process by which the participant is aware of this possibility in the event of PPP. The EQA provider should advise the participant that their identity will be disclosed to the NQAAP chair and that the NQAAP may request the laboratory's UKAS centre number.

The EQA provider should report PSEs and/or PPP, as defined in their performance criteria, to the NQAAP chair using the escalation template (document WS20503), together with copies of performance reports, actions taken by the participant and any other correspondence.

The NQAAP chair should review the referral with the relevant members of the NQAAP and provide a written course of action to the EQA provider and the participant. The actions available to the NQAAP chair are outlined in the QAPC Terms and conditions of participation of the EQA provider on the RCPath website.

The NQAAP chair should appoint a member of the NQAAP to be responsible for the coordination and oversight of the escalation process and reporting back to the EQA provider.

The EQA provider should continue to monitor and report the performance of the participant to the NQAAP chair within a week of the report of each EQA round after the PPP referral, together with any additional information and actions taken.

The NQAAP chair should liaise with the EQA provider as to whether the performance concerns have been adequately addressed prior to closing the concerns with the participant or escalating the matter further.

If the participant withdraws from the EQA programme before the performance concern has been resolved, the EQA provider should notify the NQAAP chair, with any reasons provided for the withdrawal, as described in the Scheme hopping policy (document WS20313).

5.2 Reporting performance concerns to the QAPC

If the performance concerns are not resolved to an agreed timescale or if the NQAAP chair has wider concerns over the performance of the participant, the NQAAP chair should escalate the matter to the QAPC using the PPP escalation report template (document WS20503). The NQAAP chair should notify the participant and the EQA provider of the escalation.

The QAPC will provide a written course of action to the NQAAP chair, the participant and the EQA provider.

The NQAAP chair should provide the QAPC with a report twice a year of PSEs and performance concerns referred to the NQAAP, for the purpose of sharing experience, noting trends in performance, identifying clinical and other risks, and learning points.

5.3 Reporting performance concerns to the MHRA and the CQC (or equivalent)

The QAPC chair may notify any method-related performance concerns to the MHRA even if the EQA provider has already reported the same concern to the MHRA. The QAPC chair may notify the CQC or equivalent bodies across the 4 nations if there is evidence of continued poor performance by a laboratory that is not specifically related to the

performance of a method and where patient safety may be compromised. The PPP escalation template (document WS20503) should be used to report concerns.

5.4 Reporting to other regulatory bodies

EQA providers may have arrangements for reporting performance to regulatory bodies for individual programmes or analytes, as agreed by the participant in the Terms and conditions of participation of the EQA provider.

The NQAAP and QAPC may report the performance concerns to any other regulatory body with a recognised interest in laboratory performance and patient safety in the area of testing, e.g. the UK Accreditation Service (UKAS), the Human Fertilisation and Embryology Authority (HFEA) and National Screening Programmes. Reporting can be made at any stage in the escalation procedure, at the discretion of the chair of the NQAAP or QAPC. The participant must be informed of this action.

The reporting to other regulatory bodies should be included in the actions or recommendations sections of the SBAR report as relevant to the investigation.

5.5 Reporting PSEs

Recording safety events, whether they result in harm or not, provides vital insight into what can go wrong in healthcare and the reasons why. At a national level, this allows for new or under-recognised safety issues to be quickly identified and acted on at an NHS-wide scale, ensuring providers across the country take action to reduce the risk. It also provides a wealth of data offering essential insight to support ongoing national patient safety improvement programmes, as well as improvement work at a more local or specialty-specific level.

Reporting of PSEs to the NHS National Reporting and Learning System (at the time of writing) or its successor, the Learning from Patient Safety Events (LFPSE) service, may also help build a complete picture of all risks associated with pathology testing services.

5.6 Timescales

The EQA provider should report the laboratory to the NQAAP within 2 weeks of identification of the breach of PPP criteria.

The escalation and resolution process should be complete within 3 months of the receipt of the report from the EQA provider by the NQAAP chair.

6. Review and lookback

An outcome review should be undertaken with stakeholders involved in the escalation process before the final sign-off of the performance concerns. The extent of the review will depend on the severity of the risk to patient safety and will be convened by the NQAAP chair or delegated to the NQAAP member coordinating the escalation. The outcome of the review is recorded on the PPP escalation report template (document WS20503) and will include:

- the outcome, e.g. resolution of performance concerns, withdrawal of the assay by the laboratory, identification of method-related concerns, identification of organisation-wide failure, etc.
- any lookback actions taken by the laboratory, oversight or regulatory bodies and their outcomes
- PSEs and how these have been addressed
- the lessons learnt.

7. Related documents

In addition to the documents listed in the above3. Tools section, this document should be operated with a knowledge of the documents defining error, poor performance and PPP (document WS20301) and scheme hopping (document WS20313), which are found in the Technical EQA section of the RCPath website.

The terms of reference for the operation of the NQAAPs are described in the document NQAAP terms of reference (document WS1904) and this is available in the NQAAP section of RCPath website. The Terms of reference for the QAPC are available in QAPC section of the RCPath website.

The Terms and conditions of participation of the EQA provider are described in Process for uniquely identifying a laboratory to NQAAPs (document WS10201).

The terms used are described in the Glossary of EQA terms (document WS20202).

8. Authorisation and review

Authorisation will be made by the chair of the EQA Oversight Board. The policy will be reviewed at least every 2 years and may be reviewed at any other time as need arises.