Reporting EQA performance concerns to MHRA policy

Title	Reporting EQA performance concerns to MHRA policy
Policy number	WS20901
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1. Introduction and purpose

External quality assessment (EQA) data can highlight potential performance problems related to methods. These may be identified by the EQA provider or at any other point in the pathway for the escalation of performance concerns.

This document outlines the challenges encountered by EQA providers when reporting method-related performance concerns to the Medicines and Healthcare products Regulatory Agency (MHRA) and possible solutions for improving this working relationship.

Current concerns noted by EQA providers are:

- the reporting mechanism, through the standard ‘yellow card scheme’, does not allow any distinction of concerns raised because of EQA data from general reports. The system lacks the ability to weight referrals from EQA providers.
- there is no definition of what resolution looks like for the EQA provider
- there is no inclusion of what the laboratory can do in response to a problem, e.g. where they do not have the option of changing to another kit or instrument.

Discussion through the EQA Governance Collaborative has identified two aspects of the relationship between EQA providers and MHRA that would benefit from improvement.

- A robust platform within the performance escalation process is needed where discussion of high-level, method-related performance concerns that are judged a risk to patient safety are discussed with all relevant stakeholders including instrument and in vitro diagnostics medical device (IVD) manufacturers. This platform is described in the Escalation policy (document WS20501) and associated flowchart (document WS20502) and is not covered further here.
- An improved channel of communication is needed between EQA providers and the MHRA that is based on the MHRA Yellow Card system but is tailored to EQA reporting and recognises the expertise that the EQA provider brings to the reporting process. This separate reporting process is intended for use when an EQA provider first identifies a concern and is intended to allow an early response by MHRA.

2. Scope

The document is for use by any EQA provider, the MHRA and any organisation that forms part of the EQA Governance Framework.

3. Tools

- Access to the MHRA Yellow Card reporting system (https://www.gov.uk/report-problem-medicine-medical-device).
- EQA provider template for reporting performance concerns to MHRA (document WS20902).
- The EQA Governance Collaborative Escalation policy (document WS20501) and associated documents.
- The EQA Governance Collaborative policy on managing method-related performance concerns (document WS20801).
- Guidance for EQA scheme organisers on reporting known or suspected IVD performance issues (document WS20903, see PDF version).

4. Responsibilities

4.1 EQA provider

The EQA provider will report any method-related concern to MHRA when this has been recognised (see the Reporting in vitro diagnostic medical devices concerns policy [document WS20801]).

4.2 MHRA

The MHRA will respond and manage concerns reported to the organisation by the EQA provider. Where the performance concern is escalated by one of the National Quality Assurance Advisory Panels (NQAAPs), as described in the Escalation of EQA performance concerns policy (document WS20501), the MHRA will engage proactively with the escalation review process.

The MHRA will provide feedback on the actions taken and responses from manufacturers to the EQA provider and will ensure that the concerns have been addressed before the incident is closed.

4.3 Instrument and IVD manufacturers

IVD manufacturers will engage with the MHRA and respond to the concerns raised, including meeting with the MHRA and EQA provider to discuss actions.

5. Procedure

Method-related IVD performance concerns are reported to the MHRA using the Yellow Card system (https://www.gov.uk/report-problem-medicine-medical-device), at the time of writing. Guidance for EQA providers is contained in the document Reporting in vitro diagnostic medical devices concerns policy (document WS20801).

The following adaptation is suggested for use by EQA providers to build on the current reporting.

The EQA provider will:

i. complete the EQA provider template for reporting performance concerns to MHRA (see document WS20902) and attach that to the Yellow Card report, including an assessment of clinical risk

ii. ensure the acronym ‘EQA’ is included in the free text box for describing what went wrong with the device in the Yellow Card report. The MHRA team use the keyword ‘EQA’ to perform searches and find incidents submitted by EQA scheme providers.

iii. in addition, contact MHRA directly via email when they receive the Yellow Card reference number, alerting them to the submission of an EQA report.

iv. work with the MHRA to resolve any information requests and potentially join meetings with the MHRA and IVD manufacturers to discuss IVD issues. MHRA has a standard procedure for review and actions when receiving an EQA report (see document WS20903, PDF version).

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6. 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.