

GUIDELINES FOR EQA SCHEME ORGANISERS IN THE MANAGEMENT OF PROBLEMS WITH EQA PERFORMANCE OF IN VITRO DIAGNOSTIC MEDICAL DEVICES

*Drafted for Joint Working Group on Quality Assurance by BIVDA/EQA Forum
May 2002 (references revised December 2003)*

INTRODUCTION

These Guidelines are for use by External Quality Assessment (EQA) Scheme Organisers when dealing with analytical performance which appears to be a feature of the method employed and not a result of participants' errors that could otherwise result in their referral for poor performance to a National Quality Assurance Panel (NQAAP). Such situations are best approached through constructive co-operation between all parties. However, Scheme Organisers must ensure that they do not breach the confidentiality that exists between the Scheme and all participants as defined by the Joint Working Group on Quality Assurance⁽¹⁾, nor inappropriately divulge commercially sensitive information.

The Guidelines will be made available to Scheme Organisers, product suppliers and regulators.

Scheme Organisers are encouraged to report adverse incidents promptly to the Medicines and Healthcare products Regulatory Agency (MHRA)* in accordance with the requirements in the first Medical Device Alert of each year⁽²⁾.

An adverse incident is defined as "an event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of patients, users or other persons"⁽²⁾. This includes incidents associated with in vitro diagnostic medical devices, which may be instruments, reagents and associated software. Unexpected or unwanted effects might include delayed or inappropriate diagnosis or treatment.

MHRA, an Executive Agency of the Department of Health, has responsibility for : protecting and promoting public health and patient safety by ensuring that medicines, healthcare products and medical equipment meet appropriate standards of safety, quality, performance and effectiveness, and are used safely.

* The MHRA was formed from a merger of the Medicines Control Agency (MCA) and the Medical Devices Agency (MDA) on 1 April 2003.

PROCEDURE

If the Scheme Organiser, using professional judgement, detects an apparent problem (including a change) in EQA performance for a particular measurement procedure, the actions listed below may be activated. It is not expected that all of these actions will be essential to any given case, nor are the actions listed in order of importance.

Phase 1) Investigating the extent

If a significant number of participants in the category show the problem or change the Scheme Organiser should commence an investigation in collaboration with the manufacturer/supplier, other relevant Scheme Organisers, MHRA and (where relevant) participants whose performance had previously been considered as being satisfactory. Amongst the actions that might be undertaken are:

- examine individual data for members of the method/instrument group to determine how many show the problem
- check company information for product changes that could be affecting performance
- contact laboratories affected to enquire about changes in procedures, servicing, software, IQC parameters
- determine whether the problem is seen in patients' samples as well as EQA and/or IQC materials.
- contact the manufacturer/supplier to enquire whether their technical / customer support departments have received reports of performance problems, both in the UK and in other geographical areas
- enquire of other EQA Scheme Organisers if they also observe the problem
- inform the NQAAP as part of the normal reporting mechanism; the NQAAP may in turn inform Scheme Organisers of apparent problems seen in other EQA Schemes
- the Scheme Organiser should contact the MHRA if there could be implications for clinical sample analysis (such as the potential for delayed or inappropriate diagnosis or treatment).

Phase 2) Determining the cause

- If the problem is only seen in EQA materials, with IQC and patient samples unaffected, the Scheme Organiser will need to investigate the relationship between the effects observed and the EQA materials.
- If the problem is seen in EQA and IQC materials, with patient samples unaffected, the Scheme Organiser will need to investigate the relationship between the effects observed and the EQA and IQC materials
- If the problem is seen also in patients' samples, the Scheme Organiser should, in collaboration with the manufacturer/supplier, establish the extent of use of the affected product and assist in correlation of this with the extent of effects on patients' results and EQA results.

- If new batches of the product, unaffected by a change are made available, the Scheme Organiser should facilitate comparison studies using the provision of EQA samples and advice, with the aim of restoring expected EQA performance and/or clinical results.

Phase 3) Conclusion

- All parties involved in the investigation should ensure that regular reports of progress are made available. If the cause of the problem cannot be established this fact must be reported.

When all parties are satisfied with the results of the investigation, the Scheme Organiser should give a summary report to the relevant Steering Committee or Advisory Group, the MHRA, the NQAAP and participants if appropriate.

- If the manufacturer/supplier is reluctant to agree that the problem exists and cannot show that patient results are unaffected by it, this automatically falls within the definition of an “adverse incident” and thus the remit of the MHRA. The Scheme Organiser should bring the matter to the attention of the appropriate Steering Committee / Advisory Group or equivalent and of the MHRA (even if MHRA have been notified previously) with the minimum of delay. The MHRA will determine what other actions or investigations are required to resolve the issue. The Scheme Organiser will ensure the continuation of an appropriate EQA service to all participants. The relevant National Quality Assurance Advisory Panel will be informed, and its influence used where necessary to achieve a satisfactory outcome. The NQAAP may consider seeking advice and help from the Joint Working Group on Quality Assurance (JWG).

⁽¹⁾ "Conditions of participation by UK clinical laboratories in external quality assessment schemes"

Copies of reference (1) may be obtained from the JWG Secretary

⁽²⁾ eg –Medical Device Alert MDA/2003/001 “Reporting adverse incidents and disseminating safety warnings“

Current version of reference (2) is available on the [Medicines and Healthcare products Regulatory Agency website www.mhra.gov.uk](http://www.mhra.gov.uk), or may be obtained from MHRA, tel: 020 7972 8000 email: : dts@mhra.gsi.gov.uk