Focus Article: A systematic approach for handling unacceptable EQA results

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Introduction

Medical laboratories have to ensure that the test results produced are reliable. Therefore a quality control system should be implemented. One element of such a quality control system is participation in an external quality assessment (EQA) programme. In ISO standard 15189, paragraph 5.6.3.1 it states that "*the laboratory shall participate in an inter-laboratory comparison programme(s) (such as an external quality assessment programme or proficiency testing programme) appropriate to the examination and interpretations of examination results"* [1]. An important aspect of participation in an EQA programme is the evaluation of survey reports. ISO standard 15189, paragraph 5.6.3.1 states that *"The laboratory shall monitor the results of the inter-laboratory comparison programme(s) and participate in the implementation of corrective actions when predetermined performance criteria are not fulfilled"* [1]. Proper and timely evaluation is essential. This should be done with all relevant staff and according to pre-defined performance criteria. When criteria are not met, appropriate corrective actions should be implemented and recorded (ISO standard 15189, paragraph 5.6.3.4) [1].

Recently we published in close co-operation with the Norwegian EQA provider NOKLUS a systematic approach for handling unacceptable EQA results [2]. In this focus article we give a brief summary of this systematic approach. The full publication can be downloaded with the following link:
https://doi.org/10.11613/BM.2017.007

Performance criteria

An essential element in the evaluation of EQA results is the performance criteria used. In blood coagulation, where no reference measurement procedures and certified reference materials (primary standards) are available, statistical limits can only be based on state-of-the-art standards. This means that with an appropriate statistical procedure (robust statistics) the assigned value is established on the basis of participants' results (consensus value). The performance of an individual laboratory is expressed by the Z-score. The Z-score is a standard deviation index which indicates by the number of the standard deviation the distance between the assigned value and the participant result.
The z-score is calculated as follows:

[(laboratory result) - (mean result of all laboratories)] / (standard deviation of all results)

The performance criteria used in the ECAT programme are given in table 1.

Table 1. Performance criteria used in the ECAT EQA programme

-2 ≤ Z-score ≤ 2	The result is acceptable
-3 < Z-score < -2 or 2 < Z-score < 3	The result is questionable (warning signal)
Z-score ≤ -3 or Z-score ≥ 3	The result is unacceptable (action signal)

A single action signal or two warning signals in consecutive exercises should be taken as evidence that an anomaly has occurred that requires investigation by the laboratory.
Such an investigation can be cumbersome and time-consuming and therefore requires a systematic approach.

Flowchart

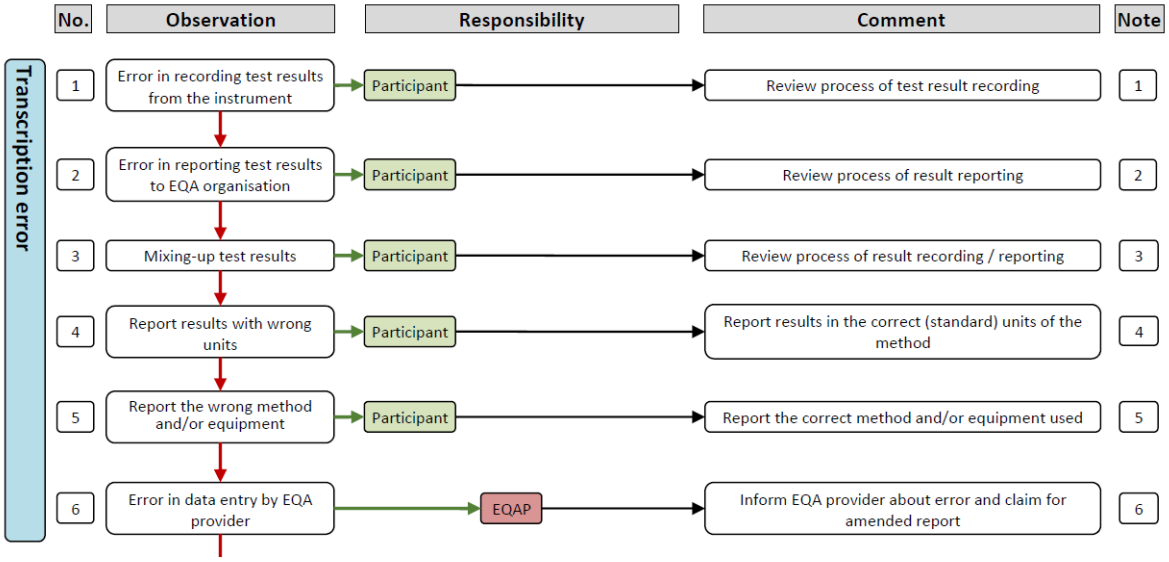
It is important to realise that a variety of factors may have caused the deviating EQA result(s). It was demonstrated by the Norwegian EQA organisation NKK that the most common cause of a deviating result was a

transcription error [2]. For this reason the flowchart starts by investigating different kinds of transcription errors. The flowchart was designed in such a way that it follows the flow of a sample during the testing process (pre-survey issues / sample receipt and handling issues / test performance issues). Furthermore, error could also be caused by inappropriate data handling by the EQA provider. The last category in the flowchart concerns issues related to the report and its interpretation.

In addition, it should also be realised that the responsibility for the error can lie with the participant in the EQA programme, the EQA provider, the manufacturer of equipment and reagent or a combination of these. The responsibilities are indicated in the flowchart.

Each item in the flowchart is elucidated by four different aspects: **Observation**: what the potential error is, **Responsibility**: who is responsible for the error, **Comment**: a short comment on the appropiate action to take, and finally, **Note:** a more detailed description of actions.
An example of the design of the flowchart is given in figure 1.

Figure1. An example of the first part of the flowchart for handling deviating EQA results.



In the notes a more detailed description of the problem is given and, where possible, advice is given on how to treat the problem.
An example of some notes is given in figure 2.

Figure 2. An example of the list of notes indicated on the flowchart for handling deviating EQA results.

Note	Remark
Pre-note	The comment letter or comment section in the report may include comments regarding remarkable observations (e.g. a relative large deviation for a specific method mean with respect to the overall assigned value). Evaluate carefully the remarks and consider whether this could be explaining your deviating result.
1	The participant had made an error in recording the test result of the EQA sample(s) and as such reported a wrong result(s). This is an internal cause for the error made. The participant should carefully review the process of result recording and take appropriate action to avoid this problem in future surveys.
2	The participant had made an error in reporting the test result of the EQA sample(s) to the EQA organisation. This is an internal cause for the error made. The participant should carefully review the process of result reporting and take appropriate action to avoid this problem in future surveys.
3	The participant had mixed-up the test results either at the level of recording the test result from the instrument or when the test results were reported to the EQA organisation. The participant should carefully review the process of result recording and/or reporting and take appropriate action to avoid this problem in future surveys.
4	The participant had reported the result with the wrong unit (e.g. report the result in U/dL instead of U/mL). This may lead to incorrect treatment of the data in the evaluation software of the EQA organiser. In this case the result could be assigned as an outlier. The participant should select the correct unit when reporting a result to avoid this problem in future surveys.

By following systematically the flow chart it is in principle possible to reveal the most likely cause for the deviating result. It should be realised that a deviating EQA result is not always caused by a single error. It could also be a multi-causal problem. If no explanation for the EQA error has been found, it may have been a transient error in the system at the time of measurement. In this case the participant should evaluate whether the error occurs in later EQA surveys again.

A detailed description about the content of the flowchart can be found in the indicated publication.

Use of the flowchart

Although different approaches are possible for finding the cause of a deviating EQA result, we believe that this flowchart may help the laboratory in their obligation to investigate the cause of a deviating EQA result.

This flowchart and the corresponding list of notes is available on the ECAT website. At the time you log in to the participant area you will find in the left-hand panel the item “Flowchart”. Here you can download both documents. We also prepared a form for evaluating deviating EQA results. This form can be used to register your investigation of the cause of the error and the actions taken (ISO 15189, paragraph 5.6.3.4) [1].

Response

If you have any comments to the flowchart or if you are willing to share with us your experience in using the flowchart, please send us an e-mail (info@ecat.nl).

References:

1. 15189, I., Medical laboratories – particular requirements for quality and competence. Geneva: International Organization for Standardization (ISO), 2012.
2. Kristensen, G.B. and P. Meijer, Interpretation of EQA results and EQA-based trouble shooting. Biochem Med (Zagreb), 2017; 27: 49-62.