The European Molecular Genetics Quality Network

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UKAS accredited
Proficiency
Testing Provider

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EMQN Procedure for monitoring laboratory performance standards (disease-specific and technical EQA schemes)

(v7, updated 2017)

1. INTRODUCTION

This procedure details the process involved in determining the performance standard of each participating laboratory, maintaining a record of participant performance and monitoring the performance year to year. It is the responsibility of the EMQN Director to monitor the performance of all EMQN participants and to take appropriate action in the event of poor performance or persistent poor performance. The following performance categories will be applied:

- Laboratories operating at an acceptable level of performance are classed as "**green**".
- Laboratories deemed to be poor performing laboratories, as defined in this document, are classed as "**amber**".
- Laboratories deemed to be persistent poor performing laboratories, as defined in this document, are classed as "**red**".
- Persistent poor performing laboratories not responding appropriately to NQAAP/Joint Working Group for Quality Assurance (JW G) action as defined by the JWG are classed as "**black**"[1].
- Poor performance criteria DO NOT apply to pilot EQA schemes.

The performance criteria for the Molecular Pathology EQA schemes are detailed in DOC2703.

2. DATA MONITORING

Performance data of each participant from 2002 to the current year are stored on the scheme website. Participants can access their own performance data via their own password protected account. They can only access their own laboratory scores. Performance data is monitored by the EMQN Director. The results submitted by each laboratory for all scheme distributions and individual laboratory scores are stored on the scheme website which is password protected. Only the EMQN Director has access to the identity of all laboratories and their performance data. A comparison of performance data between EQA rounds as well as a year-on-year comparison is performed by the EMQN Director. This includes performance in the same EQA scheme and between different EQA schemes. This ensures that any poor performance trends are identified promptly and action can be taken if deemed appropriate by the EMQN Director and the EMQN Board.

3. RATIFICATION OF CRITERIA

The criteria for identifying poor performers and persistent poor performers are ratified by the EMQN Board.

4. CRITERIA FOR IDENTIFYING POOR PERFORMERS (AMBER STATUS)

4.1 Criteria

The criteria for poor performance and persistent poor performance and the action taken when this arises have been established and are as follows:

The central purpose of external quality assurance is to ensure that laboratories are delivering a service of the highest possible quality. EMQN maintains the principle of assessment by professional consensus and attempts to improve standards by education and peer group review rather than by censure or penalty. Performance criteria are necessary to allow an individual laboratory's performance to be measured against national and international standards and to identify any laboratory that is failing to meet these criteria. Participants who fall below the standards set out here are deemed to be performing poorly. These laboratories will be classed as "amber" whilst the poor performance status stands.

Poor performance will be determined at the level of the individual scheme, rather than on the basis of the

[1] Applies to UK laboratories only

participant's average score across all schemes run by EMQN. Thus it will be possible, for example, to be a poor performer for AZF while performing well for all other diseases. However, the EMQN Director will review the laboratory's performance in all schemes when poor performance is detected and if concerned about the standard of the laboratory's service then will discuss with the EMQN Board if further action should be taken.

When a serious genotyping error is identified, the EMQN Director will contact the participant as soon as the error comes to light. In this way it is intended that any consequences of the error will be rectified by the laboratory without delay.

A variable number of clinical case scenarios with appropriate samples are distributed for each scheme, per round of EQA[2]. Poor performance (**amber status**) is calculated at the scheme level and defined as follows:

Schemes with 1 case

Category	Criterion
Genotyping	Any instance of a critical genotyping error.
Interpretation	Any instance of a critical Interpretation error (see criterion 4.2).
Patient Identifier's and Clerical Accuracy	This category does not contribute to poor performance.

Schemes with 2 cases

Category	Criterion
Genotyping	Scoring less than 1.2 as a mean Genotyping score, *and/or,* any instance of a critical genotyping error.
Interpretation	Any instance of a critical Interpretation error (see criterion 4.2).
Patient Identifier's and Clerical Accuracy	This category does not contribute to poor performance.

Schemes with 3 cases

Category	Criterion
Genotyping	Scoring less than 1.4 as a mean Genotyping score, *and/or,* any instance of a critical genotyping error.
Interpretation	Any instance of a critical Interpretation error (see criterion 4.2).
Patient Identifier's and Clerical Accuracy	This category does not contribute to poor performance.

Schemes with 4 or more cases

Category	Criterion
Genotyping	Scoring less than 1.6 as a mean Genotyping score, *and/or,* any instance of a critical genotyping error.
Interpretation	Any instance of a critical Interpretation error (see criterion 4.2).
Patient Identifier's and Clerical Accuracy	This category does not contribute to poor performance.

Interpretation and Clerical Accuracy are not assessed in Genotyping only EQA schemes. Poor performance in these schemes is determined at the genotyping category level only as per the criteria show above.

4.2 Incorrect advice given, correct advice not given

Where a report contains advice which is considered by the Scheme Organiser and Assessors to be dangerously erroneous, or when a report does not contain advice considered by the Scheme Organiser and Assessors to be essential, this will be sufficient to constitute Poor Performance.

4.3 Non-participation

Non-UK labs

EQA participation is a requirement of Laboratory accreditation to international norms (e.g., ISO17025 and ISO15189). If a laboratory registers for an EQA scheme, receives samples but fails to participate without informing the EMQN Director of a suitable reason for non-participation (in advance of the reporting deadline), then it will be deemed **a poor performer due to non-participation**.

UK labs only

Participation in each round of EQA for all diseases offered as a clinical service is a requirement of the EMQN. EQA participation is also a requirement of CPA (UK) Ltd/UKAS Medical Laboratory accreditation. Non-registration by a UK

[2] Usually 3 cases but very occasionally this may be less (2), or more (4).

laboratory for an EQA scheme for any disease offered as a clinical service by the laboratory in any round of EQA in which that disease is offered by EMQN exclusive of any other EQA provider will be deemed Poor Performance for that disease in that year. This will apply irrespective of previous performance scores for that disease. Laboratories will not be expected to continue participation for any disease no longer offered as a clinical service but should inform the EMQN Director in writing when this occurs. Failure to inform the EMQN Director will result in **poor performance due to non-participation**. The EMQN Director will follow up any non-registration of previous participants.

If a laboratory registers for an EQA scheme but fails to participate without informing the EMQN Director of a suitable reason for non-participation (in advance of the reporting deadline), then it will be deemed a **poor performer due to non-participation**.

4.4 Action following Genotyping Poor Performance

Once the scores for the EQA round have been finalised, then the EMQN Director reviews the **genotyping** scores for each participating laboratory for all EQA schemes. If any participant has fallen below the acceptable performance standard described in Section 4.1 for genotyping then the EMQN Director will contact the participant informing them of their error, their laboratory's poor performance /amber status and request that the cause of the genotyping error is investigated. Depending on the type of genotyping error made, this initial contact will be either by telephone, email or letter (determined by the EMQN Director, normally within 30 working days of the final published scheme results). The laboratory is given a defined period (determined as reasonable by the EMQN Director, normally 60 working days) in which to respond to the EMQN Director with the cause of the error. At this point the participant may feel confident about addressing the problem internally but help and advice will be made available on request. The EMQN Director will not reveal the identity of the participant to those providing such assistance unless the participant has specifically given permission to do so.

If no satisfactory response is obtained within the given time period then the EMQN Director will resend the letter by email with a further 15 working day period for a response. If the laboratory continues to fail to provide a satisfactory response then a second poor performance is designated.

If a serious genotyping error is made then the Scheme Assessment team inform the EMQN Director as soon as possible. The EMQN Director then contacts the laboratory immediately. This ensures that the laboratory is informed of the critical genotyping error within a short time frame and an investigation into the cause of the error can be initiated.

The laboratory remains a poor performing laboratory (amber laboratory) until the laboratory performs satisfactorily in the next round of EQA when their poor performance/**amber** status is removed. The poor performance remains on record.

This action will be followed for UK and non-UK participants.

4.5 Action following Interpretation Poor Performance

If any participant has fallen below the acceptable performance standard described in Section 4.1 for **interpretation** then the EMQN Director will contact the participant by letter (posted or emailed) after the appeals process informing them of their laboratory's poor performance status. The laboratory is given a defined period (determined as reasonable by the EMQN Director, normally 60 working days) in which to respond to the EMQN Director with the cause of the error. At this point the participant may feel confident about addressing the problem internally but help and advice will be made available on request. The EMQN Director will not reveal the identity of the participant to those providing such assistance unless the participant has specifically given permission to do so.

If no satisfactory response is obtained within the given time period then the EMQN Director will resend the letter by email with a further 15 working day period for a response. If the laboratory continues to fail to provide a satisfactory response then a second poor performance is designated.

The laboratory remains a poor performing laboratory (amber laboratory) until the laboratory performs satisfactorily in the next round of EQA when their poor performance/**amber** status is removed. The poor performance remains on record.

This action will be followed for UK and non-UK participants.

5. CRITERIA FOR IDENTIFYING PERSISTENT POOR PERFORMERS (RED STATUS)

5.1 Criteria

Persistent Poor Performers will be defined as either:

- those participants who perform poorly for a disease in **three** out of any **six** consecutive EQA scheme participations.

or

- those participants who perform poorly for a disease in any **two** consecutive EQA scheme participations.

Performing poorly in any **one** of these categories will count towards Persistent Poor Performance. These laboratories will be classed as "**red**" whilst the persistent poor performance status stands. Performing poorly on genotyping in one round of EQA and interpretation in the next two rounds will have the same consequences as performing poorly on genotyping for three rounds of EQA. If a participant performs poorly for more than one disease in more than one EQA, that laboratory's results will be reviewed by the EMQN Director and the EMQN Board and that participant may, at the discretion of the EMQN Board, be referred for Persistent Poor Performance even if they have not met the criteria for Persistent Poor Performance in any individual EQA.

5.2 Action following identification of a persistent poor performing non-UK laboratory

Once a non-UK laboratory reaches the criteria for Persistent Poor Performance the EMQN Director will obtain ratification of the persistent poor performance/**red** status by the EMQN Board (either at the next Board meeting, or by email). The EMQN Director will write to the laboratory informing them of the laboratory's persistent poor performance status and offer help and advice in order to improve the service provided by the laboratory. The EMQN Director will not reveal the identity of the participant to those providing such assistance unless the participant has specifically given permission to do so.

The laboratory is given a defined period (appropriate to the situation) in which to respond to the EMQN Director. If no satisfactory response is obtained within the given time period, then the EMQN Director will resend the letter by email and post (requiring a signature upon delivery) with a further 15 working day period for a response. If the laboratory continues to fail to provide a satisfactory response, then the EMQN Director will telephone the primary contact of the laboratory to seek the required information. If contact is not successful, then the EMQN Director will discuss the situation and suitable action with the EMQN Board at the next meeting (or by email if the next meeting is scheduled more than 3 calendar months' time). The identity of the laboratory will not be disclosed to the EMQN Board. The EMQN Board will decide when the persistent poor performance/**red** status of the laboratory can be removed. The persistent poor performance will remain on record.

5.3 Action following identification of a Persistent Poor Performing UK laboratory

Once a UK laboratory reaches the criteria for Persistent Poor Performance the EMQN Director is obliged to notify the National Quality Assessment Advisory Panel (NQAAP) for Genetics. The EMQN Director will obtain ratification of the persistent poor performance/**red** status by the EMQN Board (either at the next Board meeting, or by email). The EMQN Director will contact the Chairman of NQAAP for Genetics with details of the laboratory's performance. The identity of the laboratory will be revealed to the panel and subsequently the Joint Working Group for Quality Assurance (JWG). The EMQN Director will write to the laboratory informing them of the referral to NQAAP.

The Panel will consider the best approach to improve the situation and will contact the laboratory directly, requesting a response by a specific date. The NQAAP Chairman should agree in writing any remedial action to be taken and the timescale and responsibility for carrying this out. If appropriate, this letter will be copied to accreditation/regulatory bodies such as CPA (UK) Ltd, UKAS and HFEA who may arrange an urgent visit to the laboratory. Advice is offered to the Head of the Laboratory in writing or, if appropriate, a visit to the Laboratory from a NQAAP member or appropriate agreed expert(s) may be arranged.

If persistent poor performance remains unresolved, the laboratory will be classed as "**black**" and the NQAAP Chairman will submit a report to the Chairman of the JWG giving details of the problem, its causes and the reasons for failure to achieve improvement. The Chairman of the JWG will consider the report and, if appropriate, seek specialist advice from a panel of experts from the appropriate professional bodies to advise him/her on this matter. The Chairman of the JWG will be empowered to arrange a site meeting of this panel of experts with the Head of the Department concerned. If such supportive action fails to resolve the problems and, with the agreement of the panel of experts, the Chairman of the JWG will inform the Chief Executive Officer, or nearest equivalent within the organisation of the Trust or Institution, of the problem, the steps which have been taken to rectify it and, if it has been identified, the cause of the problem.

The Chairman of the JWG also has direct access and responsibility to the Professional Standards Unit of the Royal College of Pathologists. Should these measures fail to resolve the issues; the laboratory will be referred to the Care Quality Commission for further action. The Chairman of NQAPP-Genetics will notify the EMQN Director when the persistent poor performance/**red** status of the laboratory can be removed. The persistent poor performance will remain on record.

6. ADDITIONAL INFORMATION (UK LABS)

EMQN's experience suggests that referral to NQAAP will be very infrequent, since the majority of laboratories will correct any deficiencies before reaching that stage in the procedure. This is as it should be, since the consequences of a referral to NQAAP are serious, with implications for CPA (UK) Ltd/UKAS accreditation as well as the obvious doubts that must arise about the quality of service to patients.

7. CROSS REFERENCES

- DOC2649 Report to UK NQAAP
- DOC2703 EMQN Procedure for monitoring laboratory performance standards (molecular pathology)
- DOC2705 Poor performance letter
- DOC2706 EQA scheme appeals procedure

8. SUMMARY OF CHANGES TO DOCUMENT

Version no.	Change(s)
1	New document
2	Rewording to make simpler. Version no. updated
3	Updated to include poor performance for non-participation along with criteria for persistent poor performance.
4	Updated header and added UKAS logo
5	Complete rewrite to harmonise with UK schemes and requirements for reporting to JWG / NQAAP.
6	Updated with new criteria for PP based on number of cases (section 4.1). Also highlighted non-submission of results will also count to PP (section 4.3)
7	Criteria for PPP (section 5.1) now refer to subsequent EQA scheme participations rather than subsequent rounds of EQA