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

(v12, updated May 2024)

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. This includes performance in the same disease/disorder EQA and, at the discretion of the EMQN Scientific and Strategic Advisory Board (SSAB), between disease/disorder EQAs. It is the responsibility of the EMQN CIC Chief Executive Officer (CEO) to monitor the performance of all EMQN CIC 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 (JWG) 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 CIC CEO, the Technical and Operations Director/Quality Manager and designated deputies. The results submitted by each laboratory for all scheme distributions and individual laboratory scores are stored on the scheme website which is password protected. The EMQN CIC CEO and the Technical and Operations Director/Quality Manager have 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 CIC CEO and the Technical and Operations Director/Quality Manager. 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 CIC CEO and the EMQN CIC SSAB.

3. RATIFICATION OF CRITERIA

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

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

4. CRITERIA FOR IDENTIFYING POOR PERFORMERS (AMBER STATUS)

4.1 Criteria

The central purpose of external quality assurance is to ensure that laboratories are delivering a service of the highest possible quality. EMQN CIC 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. Poor performance is restricted to errors or omissions that could lead to serious clinical consequences or imply a significant lack of diagnostic skill or scientific knowledge on the part of the participating laboratory. These laboratories will be classed as “amber” whilst the poor performance status stands.

¹ Applies to UK laboratories only

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Operation of EQA schemes: A variable number of clinical case scenarios with appropriate samples are distributed for each scheme, per round of EQA. Participant reports are assessed by expert assessors using a deductive marking system (maximum score 2.0 marks), which incorporates educational feedback comments. Poor performance (amber status) is calculated at the scheme level and defined as follows:

All schemes, Except NGS Schemes (see below)*

Category	Criterion
Genotyping	Any instance of a critical genotyping error (2.0 marks deduction).
Interpretation	Any instance of a critical Interpretation error (see criterion 4.2) (2.0 marks deduction) *.
Patient Identifiers 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 shown above.

NGS schemes*

Performance is assessed in terms of NGS data quality using the F-score. The marking system covers:

- NGS variant concordance using the F-score for single nucleotide polymorphisms (SNPs) only, within the high-confidence regions of the genome. Any instance of an F-Score below the 90% threshold will result in the overall performance of the laboratory to be classified as poor. The performance outcome for this EQA is Satisfactory OR Poor. The EMQN and GenQA staff will ensure consistency of scoring between and within the EQA rounds.
- **Notes:**
 - High confidence' is defined as genomic regions exclusive of union of all tandem repeats, all homopolymers >6bp, all imperfect homopolymers >10bp, all difficult to map regions, all segmental duplications, GC <25% or >65%, "Bad Promoters", and "Other Difficult Regions" as published by NIST in Genome In A Bottle - Genome Stratifications (<https://doi.org/10.18434/M32190>).
 - The F-score of indels (<50bp) is excluded from the current Performance Criteria.

Poor performance will be determined at the level of the individual scheme, rather than on the basis of the participant's average score across all schemes run by EMQN CIC. Thus, it may be possible, for example, to be a poor performer for the Lung cancer scheme while performing well for all other schemes. However, the EMQN CIC CEO will review the laboratory's performance in all schemes when poor performance is detected. At the discretion of the SSAB, persistent poor performance may be awarded for poor performance within multiple schemes in the same year, particularly where this is detected in related schemes e.g., inherited cancers or molecular pathology; any concern regarding the standard of the laboratory's service will be discussed with the EMQN CIC SSAB.

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 and/or withdraw from the scheme without informing the EMQN CIC CEO 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**.

Laboratories which fail to reregister for schemes in subsequent years will be sent reminders to participate by EMQN CIC.

UK labs only

Participation in each round of EQA for all diseases offered as a clinical service is a requirement of the EMQN CIC. EQA participation is also a requirement of UKAS Medical Laboratory accreditation. Non-registration by a UK 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 CIC 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 CIC CEO in writing when this occurs. Failure to inform the EMQN CIC CEO will result in **poor performance due to non-participation**. The EMQN CIC CEO 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 CIC CEO 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 or Interpretation Poor Performance

EMQN CIC publishes the validated genotypes within 2 weeks of the closing of the assessment period to allow laboratories to 'self-assess' issues with the quality of their service. However, if a serious issue with genotyping is identified, during the 'marking period', the EMQN CIC CEO 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.

Once the scores for the EQA round have been finalised, then the EMQN CIC CEO reviews the **genotyping and interpretation**

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Version 12	Page 2 of 4

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 or interpretation**, then the EMQN CIC CEO 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 CIC CEO, normally 60 working days) in which to respond to the EMQN CIC CEO 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 CIC CEO 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 CIC CEO 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 for a minimum of four years.

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

4.5 Late Appeals

On very rare occasions, a laboratory may appeal their results after the closing of a scheme, and the assignment of poor performance. It is not usual practice to accept late appeals, however, where the appeal involves poor performance and/or there is a possibility that a mistake has been made in their marking, an appeal may be considered by the SSAB. In such cases it is important for the laboratory to show why they were unable to respond during the formal appeals period and to provide necessary evidence to accompany the appeal. Processes are in place for reissue of results and the withdrawing of poor performance communications (DOC3070).

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

These laboratories will be classed as "**red**" whilst the persistent poor performance status stands. 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 CIC CEO and the EMQN SSAB and that participant may, at the discretion of the EMQN CIC SSAB, 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 CIC CEO will obtain ratification of the persistent poor performance/**red** status by the EMQN CIC SSAB (either at the next Board meeting, or by email). The EMQN CIC CEO 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 CIC CEO 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 CIC CEO. If no satisfactory response is obtained within the given time period, then the EMQN CIC CEO 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 CIC CEO will telephone the primary contact of the laboratory to seek the required information. If contact is not successful, then the EMQN CIC CEO will discuss the situation and suitable action with the EMQN CIC SSAB 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 CIC SSAB meeting. The EMQN CIC SSAB 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 CIC CEO is obliged to notify the National Quality Assessment Advisory Panel (NQAAP) for Genetics. The EMQN CIC CEO will obtain ratification of the persistent poor performance/**red** status by the EMQN CIC SSAB (either at the next Board meeting, or by email). The EMQN CIC CEO 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 CIC CEO 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 UKAS and

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Version 12	Page 3 of 4

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. For more information please see <https://www.rcpa.org/resourceLibrary/joint-working-group-on-quality-assurance-conditions-of-eqa-scheme-participation.html>.

6. ADDITIONAL INFORMATION (UK LABS)

EMQN CIC'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 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
- DOC2704 EMQN CIC Procedure for monitoring laboratory performance standards (Disease specific and technical EQA schemes)
- DOC2705 Poor performance letter
- DOC2706 EQA scheme appeals procedure
- DOC3070 Procedure for generating, reviewing, releasing and monitoring EQA performance data

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
8	PP due to mean genotyping score has been removed. Only a critical genotyping error will contribute to PP. Section 4.1 has been updated to reflect this change including removal of cases specific tables.
9	Removed part of section 5.3 related to JWG T&Cs of EQA scheme participation and referenced the relevant RCP document (DOC4265; checked May 2018).
10	Simplified Section 4 criteria for identifying PP 'amber' status, added note 4.5 on late appeals/withdrawing PP status, section 5 updated to be more harmonized with GenQA. Changed UKAS logo and updated EMQN CIC address
11	Internal change
12	Updated EMQN logo