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PROCEDURE TO ASSESS PERFORMANCE IN THE GENETICS MICROARRAY EQA SCHEME

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1 Performance Criteria

This document details the process involved in determining the performance standard of laboratories participating in the Microarray EQA scheme.

A laboratory's performance is externally assessed by its response to validated test materials distributed by the EQA scheme (including specimens, images or case scenarios) or by retrospective examination of its own diagnostic materials (including images, reports or letters). Performance is assessed in terms of analytical and interpretive achievement.

1.1 Outline of Marking System

The marking system covers:

- analytical accuracy,
- interpretation of the results
- clerical accuracy.

The total score for each category is 2 points. The measurement of performance will typically take the form of penalty points, *e.g.* -0.5, -1.0 or -2.0, which reflect the scale of error or omission. The Scheme Director will ensure consistency of scoring criteria between Microarray EQA rounds.

1.2 Performance categories

There are only two categories of performance for any EQA: "**satisfactory**" and "**poor**". A specific set of performance criteria (marking criteria) are designed for each EQA case, based on the problems posed by the particular circumstances of that case.
The performance criteria are carefully drawn up by specialist advisory groups to reflect the expectations of current professional and best practice guidelines and ISO standards, if applicable.

1.3 Categories of errors identified in performance

The performance criteria are designed to identify errors or omissions that are defined as "**critical"** or "**non-critical"**.

A "**critical error**" is an error made in either the analytical or interpretive category 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. All **critical errors** are given 2 penalty points (i.e. a zero score) and are categorised as "poor performance". A critical error in one category may result in the remaining categories being left unmarked.

1.3.1 Critical analytical performance examples include:

- an incorrect analysis.

The interpretive performance may not be scored if a critical error is identified in the Analytical Performance category, as it is not possible to assess the interpretation of an incorrect analysis

1.3.2 Critical interpretive Performance examples include:

Interpretive considerations might include:

- failure to interpret the significance of the results correctly (including over-interpretation or making inappropriate conclusions based on the material available),
- provision of a report which is dangerously inaccurate.

A "**non-critical**" error would not be expected to have serious clinical consequences but would still be consistent with a lack of diagnostic skill, communicative ability or scientific knowledge. Non-critical errors will not result in zero scores or a poor performance categorisation either individually or by accrual.

Errors in the clerical accuracy category accrue penalties but do not contribute towards a poor performance designation. Errors in the EQA submission process attract comments but are not marked.

1.4 Appeals

There is an appeals procedure available to participants who disagree with their performance score. This is described in the documentation that accompanies the individual laboratory reports. The laboratory must appeal to the Scheme Director within two weeks of receipt of their individual laboratory report and include all supporting documentation with the appeal. The Specialist Advisory Group will review any appeals and make a final decision. The appeals process can take up to two months. The Scheme Director will contact the Head of Department with the outcome of the appeal as quickly as possible.

2 Performance Classification and definition

It is the responsibility of the Scheme Director to monitor the performance of all CEQAS participants and to take appropriate action in the event of poor performance or persistent poor performance.

The following categories will be applied:

- Laboratories operating at a satisfactory level of performance are classed as "**green**".
- Laboratories with a single poor performance as defined in this document, are classed as "**amber**" section 2.1.
- Laboratories deemed to have persistent poor performance over sequential EQAs or multiple poor performances, as defined in this document, are classed as "**red**", section 2.2.
- Laboratories with persistent or multiple poor performance that do not respond appropriately to input from National Assurance bodies (e.g. FOPH, Switzerland, NQAAP, UK) are classed as "**black**", section 2.3.

2.1 Poor Performance due to a single occurrence (amber status)

2.1.1 "Critical" errors identified in performance

Critical errors **(see Section 1.3)** will be reviewed and agreed by the Scientific Advisory Board**.** One or more **critical** error in any EQA round will normally result in a poor performance designation.

When an error of clinical significance to patient management is identified from a laboratory's EQA submission ('wet sample' EQAs only), and confirmed by the assessors, the Scheme Director will inform that laboratory as soon as is practical. In this way it is intended that any consequences of an internal laboratory error will be rectified without delay.

Poor performance will be notified to the laboratory in its individual laboratory report. There is an appeals procedure if the laboratory disagrees (Section 1.4).

Following the appeals process, if any participant has fallen below the acceptable performance standard described in this document for analysis and/or interpretation then the Scheme Director will contact the participant informing them of their error, their laboratory's amber status and request that the cause of any

critical error is investigated. Depending on the type of error made, this initial contact will be either by telephone, email or letter (determined by the Scheme Director, normally within 10 working days). The laboratory is given a defined period (determined as reasonable by the Scheme Director, usually 15 working days) in which to respond to the Scheme 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 Scheme Director will not reveal the identity of the participant to those providing such assistance unless the participant has specifically given permission to do so.

In some countries a National Assurance body exists (e.g. NQAAP) that requires additional EQA material distributed to, or requested from, the laboratory following a critical error. These distributions are designed to address the particular issue(s) that were identified during the previous EQA round(s). If performance from these additional rounds is satisfactory, conditions of participation will revert to those of other laboratories in the Scheme (i.e. no longer an active poor performance designation), although that designation will remain on record for 36 months. If performance in these additional EQA rounds is categorised as a poor, i.e. there are further critical errors or omissions, then the laboratory will be designated a **persistent poor performer** (red status -See Section 2.2).

2.1.2 Non-Registration

This only applies to countries where EQA participation is a requirement for accreditation. Registration in interlaboratory comparison programmes, such as EQA for all referral categories/diseases offered as a clinical service is a requirement of ISO15189 and the OECD guidelines. The Scheme Director will follow up any non-registration of previous participants requesting them to enrol for the EQA. Laboratories will not be expected to continue participation in EQA for a tissue/disorder/disease if it is no longer offered as a clinical service, However, they should inform the EQA in writing when such a service change occurs.

2.1.3 Non-Participation

If a laboratory registers for an EQA scheme but does not participate, poor performance will be applied due to non-participation.

Late submissions online of data or materials, where no reasonable explanation has been communicated **beforehand** to the Scheme Director will also constitute poor performance for that distribution and any documentation submitted via the post will also be returned.

2.1.4 Non-Compliance

Laboratories will be expected to respond to a poor performance notification sent by the Scheme Director, whether this is a recommendation to review the laboratory analytical or report procedures (laboratories will be normally given 15 working days to respond) or the completion of additional EQA rounds. If a laboratory fails to complete the additional EQA rounds, this will trigger a persistent poor performance designation status (Section 2.2).

2.2 Definition of Persistent Poor Performance (red status)

This is defined as:

a) Two poor performances in any microarray EQA in which the laboratory participates, over three or more distributions of material, within a 36 month rolling period;
b) Poor performance in an additional EQA distribution made to a laboratory in a country with a National advisory panel (see Section 2.1.1.1);
c) A poor performance within one year following a previous persistent poor performance designation.

Route (b) aims to identify a persistent problem in a specific aspect of service very quickly; and route (c) aims to identify any recurrence of a problem quickly.

A comparison of participant performance data between EQA rounds including year-on-year comparison is performed by the Scheme. This includes performance in the same EQA scheme and between the constitutional, haematology-oncology, microarray, PGD and MRA EQA schemes if appropriate. This ensures that any poor performance trends are identified promptly and action can be taken if deemed appropriate by the Scheme Director and the CEQAS Scientific Advisory Board.

Persistent poor performance is ratified by the CEQAS Scientific Advisory Board.

2.2.1 Action following identification of a persistent poor performing laboratory with Intervention by a National Assurance Body (FOPH, NQAAP)

This will only happen in cases of persistent poor performance (see Section 2.2 and notes). Once a Swiss or UK laboratory reaches the criteria for a persistent poor performance, the Scheme Director is obliged to notify FOPH (Swiss) or NQAAP for Genetics (UK) respectively.

The Scientific Advisory Board will decide when the active persistent poor performance (red status) of the laboratory can be removed. The persistent poor performance will remain on record.

2.2.1.1. Federal Office of Public Health (FOPH) referral

A persistent poor performance designation (red status) will lead to a further contact by the Scheme Director informing them of the referral to the Chairman of FOPH and that the laboratory's identity will be revealed to the panel. The laboratory identity will remain confidential to the panel at all times. FOPH will assess each referral, taking into account the magnitude of the problem, the laboratory's previous record, its response to the contact by the Scheme Director, and other considerations; and will make a response directly to the head of the referred laboratory. The FOPH 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 SAS (Swiss Accreditation Service) who may arrange an urgent visit to the laboratory.

2.2.1.2 NQAAP referral

A persistent poor performance designation (red status) will lead to a further contact by the Scheme Director informing them of the referral to the Chairman of NQAAP (Genetics) and that the laboratory's identity will be revealed to the panel. The laboratory identity will remain confidential to the panel at all times. NQAAP will assess each referral, taking into account the magnitude of the problem, the laboratory's previous record, its response to the contact by the Scheme Director, and other considerations; and will make a response directly to the head of the referred laboratory. 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 and UKAS 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.

NQAAP may request copies of the laboratory's reports, or standard operating procedures, for review; in which case, a team of assessors will examine these documents, and make recommendations about their accuracy, completeness, suitability and/or effectiveness to the Scientific Advisory Board; which in turn will report its considered conclusions to NQAAP via the Scheme Director.

All cases of persistent poor performance are also reported by the NQAAP Chair to the Joint Working Group on Quality Assurance (JWG). This is for information only and the identity of the laboratory will remain confidential to members of the JWG.

The Chairman of NQAAP-Genetics will notify the Scheme Director when the active persistent poor performance (red status) of the laboratory can be removed. The persistent poor performance will remain on record.

2.2.2 Action following identification of a persistent poor performing laboratory where these is no National assurance body.

Once a laboratory reaches the criteria for Persistent Poor Performance (see Section 2.2) and this is ratified by the Scientific Advisory Board, the Scheme 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 Scheme 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 Scheme Director. If no satisfactory response is obtained within the given time period then the Scheme 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 Scheme Director will telephone the primary contact of the laboratory to seek the required information. If contact is not successful then the Scheme Director will discuss the situation and suitable action with the Scientific Advisory Board by email. The identity of the laboratory will not be disclosed to the Scientific Advisory Board.

2.3 Action for intervention by the Joint Working Group (black status) – UK labs only

If persistent poor performance remains unresolved or there is no response from the laboratory, 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 Scheme Director when the active persistent poor performance (black status) of the laboratory can be removed. The persistent poor performance will remain on record.

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Notes:

1. Experience in the scheme suggests that referral to National Advisory Bodies 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 National Advisory Bodies are serious, with implications for CPA/UKAS accreditation as well as the obvious doubts that must arise about the quality of service to patients.
2. Abbreviations: CPA: Clinical Pathology Accreditation; EQA: External Quality Assessment; ISO: International Organisation for Standardization; NQAAP: National Quality Assurance Advisory Panel; OECD: Organisation for economic co-operation and development; FOPH: Federal Office of Public Health; UKAS: United Kingdom accreditation service.