

PROCEDURE TO ASSESS PERFORMANCE AND POOR PERFORMANCE IN THE CLINICAL CYTOGENETICS CONSTITUTIONAL SCHEME

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A. Performance Criteria

For each EQA round, a laboratory's performance is externally assessed by retrospective examination of its own diagnostic materials (including microscope preparations, images, reports or letters); or by its response to validated test materials distributed by the EQA Scheme (including specimens, microscope preparations, images or case scenarios). Performance is assessed in terms of technical, analytical and interpretative achievement.

For each round, the EQA Scheme will produce a specific set of performance criteria to reflect the assessment objectives of that particular round. These criteria will identify errors or omissions that are "critical", i.e. which could lead to serious clinical consequences, and imply a significant lack of diagnostic skill or scientific knowledge; And errors or omissions that are "non-critical", i.e. which may not have serious clinical consequences, but still imply a lack of diagnostic skill or scientific knowledge. The measurement of performance will typically take the form of penalty points, e.g. -0.2, -0.5, -1.0 or -2.0, which will reflect the scale of error or omission. The performance criteria will reflect the expectations of current Professional and Best Practice Guidelines (UK, or European Guidelines, as relevant). The Scheme Organiser will ensure consistency of scoring criteria between EQA rounds.

Clerical errors will be noted, but unless they contribute to an error that is deemed "critical" or "non-critical", these will not normally attract penalty points.

1. Technical Performance

Technical considerations might include: preparations that are of insufficient quality for reason for referral, consistent under- or over-scoring of preparative quality, or technical parameters that are outside expected norms (eg. quality of banding, or mitotic index). The Scheme Organiser can formally write to the laboratory and offer assistance to improve technical quality if Assessors consider that it is an outlier compared to the expected performance.

2. Analytical Performance

Analytical considerations might include: undertaking insufficient (or excessive) analysis for the reason for referral, missing or incorrectly identifying an abnormality, inventing an abnormality, inaccurate breakpoint assignment by more than two bands at the ~550 bands per haploid set, ISCN errors (major, which could affect interpretation; or minor errors), or failure to provide a written description of karyotype (the one exception being the description of foetal sex in prenatal samples).

3. Interpretative Performance

Interpretative considerations might include: failure to interpret the karyotype correctly (which might include over-interpretation or jumping to conclusions based on the material available), failure to provide a correct

clinical interpretation of the cytogenetic findings (eg. incorrect syndrome, or failure to consider an alternative interpretation), failure to include appropriate clinical advice or the provision of inaccurate advice (eg. for onward referral, requests for parental bloods or confirmatory tissue, or inappropriate recurrence risk), or a badly written report which is ambiguous or potentially misleading.

If the analysis of a case falls below the standards set, or is considered to be wrong, then the interpretation of that case will not be scored.

B. Definition of Poor Performance

1. “Critical” Errors Identified In Performance

Errors and omissions are categorised as “critical” if they could have serious clinical consequences, and imply a significant lack of diagnostic skill or scientific knowledge.

One or more critical errors 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 own material distribution, and confirmed by the Steering Committee, the Scheme Organiser will inform that laboratory as soon as is practical.

Critical errors will be reviewed and agreed by the Steering Committee.

A poor performance will be notified to the laboratory in its individual laboratory report. All the individual laboratory reports are issued simultaneously on completion of a particular EQA round. There is an appeals procedure if the laboratory disagrees with their performance score, and this is described in the documentation that accompanies the individual laboratory reports. The laboratory must appeal to the Scheme Organiser within 2 weeks of receipt of their individual laboratory report, and include all supporting documentation with the appeal. The Steering Committee/Executive will review any appeals and make a final decision. The appeals process can take up to two months. The Scheme Organiser will write to the Head of Department with the outcome of the appeal, as quickly as possible. .

The Scheme Organiser will initially contact the Head of the Department when his/her laboratory has a poor performance round, to discuss the performance issue, offering support and explaining the next steps in the assessment process. At this point the laboratory may feel confident about addressing the problem internally, but help and advice will be available on request. The Scheme Organiser will not reveal the identity of the laboratory to those providing such assistance unless the laboratory has specifically given permission to do so.

Normally the process for a critical error will involve additional EQA material distributed to, or requested from, the laboratory. 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, although the poor performance categorisation will remain on record for 3 years. If performance in these additional EQA rounds is poor, i.e. there are critical errors or omissions, then the laboratory will be designated a **persistent poor performer** (see Section C).

2. “Non-Critical” Errors Identified In Performance

Errors and omissions are categorised as “non-critical” if they are unlikely to have serious clinical consequences, but still imply a lack of diagnostic skill or scientific knowledge.

One or more non-critical errors in any EQA round will **not normally result in a poor performance designation**; although the laboratory’s report will indicate all the errors incurred, and the Scheme Organiser will monitor the extent of non-critical errors between laboratories and rounds to identify those laboratories with recurrent problems. The Laboratory can appeal non-critical errors, following the procedure in B1. Any laboratory that accumulates multiple non-critical errors, or is persistently borderline in its performance, will be reviewed by the Steering Committee, and the Scheme Organiser may write to that laboratory to offer help and advice. See also Section (4) on Non Compliance

3. Non-Participation

Non-participation in any aspect of the Scheme for which the laboratory offers a service is classed as **poor performance**. Late returns of data or materials not due to postal delay, where no reasonable explanation has been communicated **beforehand** to the Scheme Organiser will also constitute **poor performance** for that distribution and the work will be returned.

If the EQA laboratory's judgement of a case is that it is un-analysable, the Scheme Organiser will review the slides. If the Scheme Organiser concurs that the quality of the EQA material is unsatisfactory, another EQA case will be substituted. If the Scheme Organiser considers the quality adequate to obtain a result the slide will be returned to the laboratory to complete the analysis within the submission deadline.

4. Non-Compliance

A laboratory is expected to respond within two months to any significant recommendations given in the final post appeals EQA report. Failure to respond will result in a poor performance designation.

A laboratory will be expected to respond to a poor performance notification send by the Scheme Organiser, whether this is the completion of additional EQA rounds, or a recommendation to review the laboratory analytical or report procedures – Laboratories will be given 28 days to respond. If a laboratory fails to complete the additional EQA rounds, this will trigger a persistent poor performance designation. If the laboratory receives a recommendation to review their analytical or reporting policy but fails to inform the Scheme Organiser about what changes have been made, this will trigger a further poor performance.

Three or more warnings for the same omission/oversight within and/or across EQA rounds within a three-year rolling period will normally result in a poor performance designation.

C. Definition of Persistent Poor Performance

This is defined as:

- 1) poor performance in any tissue and/or combination of tissues in which the laboratory participates, over 3 or more distributions of material, within a 3 year rolling period;
 - 2) poor performance in an extra round of distribution made to a laboratory because of a poor performance designation;
 - 3) a poor performance within one year following a previous persistent poor performance designation.
- Route (2) aims to identify a persistent problem in a specific aspect of service very quickly; and route (3) aims to identify any recurrence of a problem quickly.

D. Action for Intervention by the Scheme Organiser and National Quality Assurance Advisory Panel (NQAAP)

This will only happen in cases of Persistent Poor Performance (see Section C). Referral to NQAAP only applies to UK laboratories. For non-UK laboratories, the Scheme Organiser will offer constructive feedback and will provide educative support if possible to help the laboratory overcome its performance problems, and will refer the laboratory to the Steering Committee.

1. Failure of the laboratory to improve its performance following assessment of additional EQA rounds will lead to a further contact by the Scheme Organiser, and referral to the Chairman of NQAAP. The Scheme Organiser will inform the participant of the referral and will reveal the laboratory's identify to the panel. This 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 Organiser, and other considerations; and will make a response directly to the head of the referred laboratory.

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 made recommendations about their

accuracy, completeness, suitability and/or effectiveness to the Steering Committee; which in turn will report its considered conclusions to NQAAP via the Scheme Organiser.

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

2. In the unlikely event that there is no response from the laboratory or persistent poor performance continues, the NQAAP Chair will consider writing directly to the Head of the Department and if appropriate the Chief Executive and/or Medical Director of the host Trust. The panel Chair may also request a visit to the laboratory by two NQAAP members.

The panel Chair will also report the laboratory as an unresolved Persistent Poor Performer to the JWG for advice. The Chairman of the JWG will consider the report and, if appropriate, seek specialist advice from a Panel of experts from 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 problem and, with the agreement of the Panel of experts, the Chairman of the JWG will inform the Medical Director, 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

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