

## **CRITERIA 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 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 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 sex chromosomes in prenatal samples).

#### **3. Interpretative Performance**

Interpretative considerations 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 and will therefore incur the maximum interpretative penalty point.

## **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. There is an appeals procedure if the laboratory disagrees with their performance score. The laboratory must appeal to the Scheme Organiser within 3 weeks of receipt of their individual laboratory report, and include all supporting documentation with the appeal. The Steering Committee/Executive (SC/SCE) will review any appeals and make a final decision. A response is required from at least three members of the SC including one member of the SCE. The Scheme Organiser will write to the head of laboratory with the outcome of the appeal. The appeals process can take a few months.

The Scheme Organiser will initially contact the head of laboratory 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. For UK laboratories, the process will normally 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). No additional EQA material will be sent to non-UK laboratories.

### **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 will be expected to respond to any recommendations given in its reports. If, after a reasonable period of time it does not act upon such recommendations, that laboratory will lose marks in future EQA rounds. The Steering Group considers that three months from receipt of an EQA report which includes recommendations, or from the time when any appeal about these recommendations is completed, whichever is the longer, constitutes a reasonable period of time.

**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; or 2) poor performance in an extra round of distribution made to a laboratory because of a poor performance designation. This latter route aims to identify a persistent problem in a specific aspect of service very quickly; or 3) A poor performance within a year following a previous persistent poor performance categorisation

### **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 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 laboratory will be identified by name, and the Scheme Organiser will inform the participant of the referral. NQAAP will consider each referral, bearing in mind the magnitude of the problem, the laboratory's previous record, its response to the contact by the Scheme Organiser, and other considerations. If NQAAP decides to make contact with the laboratory, the Panel Chairman will write to the head of laboratory in the first instance.

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 Steering Committee Chair.

If there is no response or persistent poor performance continues, the NQAAP Chairman will then write directly to the Head of the Department and if appropriate the Chief Executive and/or Medical Director of the host Trust. If the above do not produce a satisfactory resolution, the Chairman of the Panel may request a visit to the laboratory by two NQAAP members.

**2. In the unlikely event that the laboratory becomes an 'Unresolved Persistent Poor Performer'**, the Chairman of the Panel will write to the Joint Working Group for advice. The Joint Working Group has written standard procedures for dealing with Unresolved Persistent Unsatisfactory Performance, which would be invoked in such circumstances. The identity of the laboratory will be revealed to the Joint Working Group.

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