



UK NEQAS FOR CLINICAL CYTOGENETICS
UK NATIONAL EXTERNAL QUALITY ASSESSMENT SCHEMES

CPA

Accredited EQA Scheme
Reference No: 086

NATIONAL EXTERNAL QUALITY ASSESSMENT SCHEME IN CLINICAL CYTOGENETICS

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PARTICIPANTS' MANUAL 2012

UK NEQAS, John Radcliffe Hospital, Oxford

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1.0 BACKGROUND

The External Quality Assessment (EQA) Scheme in Clinical Cytogenetics was established in the UK, in 1982 through the Association of Clinical Cytogeneticists (ACC). In 1983 the Scheme became affiliated to, and recognised as, a 'pilot' External Quality Assessment (EQA) Scheme in Clinical Cytogenetics by the UK National External Quality Assessment Schemes (UK NEQAS) Executive. In 1984 the UK NEQAS for Clinical Cytogenetics Scheme became a fully established Scheme within UK NEQAS. The Scheme is accredited to CPA(UK) Ltd Standards.

UK NEQAS aims to:-

- provide professionally-led and scientifically-based EQA schemes with primarily an educational objective;
- help the laboratory appraise its performance and monitor improvements externally;
- achieve this through continuous operation, frequent distributions of samples and performance feedback;
- produce reports which are designed to be clear, informative, intelligible and structured to assist interpretation and use by different levels of laboratory staff;
- assess technical, analytical and interpretative performance of a laboratory.

Details of all schemes overseen by UK NEQAS are available from the UK NEQAS office, PO Box 401, Sheffield S5 7YZ, tel 0114 261 1689, fax 0114 261 1049 or on the website at <http://www.ukneqas.org.uk>.

2.0 UK NEQAS for CYTOGENETICS

2.1 LOCATION & ADMINISTRATION

The Clinical Cytogenetics Scheme is currently based at the Women's Centre, John Radcliffe Hospital in Oxford. The John Radcliffe Hospital is part of the Oxford University Hospitals NHS Trust.

UK NEQAS for Clinical Cytogenetics is administered through the Directorate of Critical Care, Theatres, Diagnostics and Pharmacy within the Trust but is independent from pathology services provided by the Trust.

Financial administrative services for the Cytogenetics Scheme are provided by the

Finance Department at Manor House Annexe, Oxford University Hospitals NHS Trust. The Scheme Organiser is the budget holder for the Scheme and obtains advice and support from Mr Nigel Byng (Finance Manager).

The Scheme buys IT support from the Trust and also pays an annual 'hotel charge' which covers other service costs.

2.2 COMMUNICATIONS

The **postal** address is:

UK NEQAS for Clinical Cytogenetics
Women's Centre
John Radcliffe Hospital
Headington, OXFORD, OX3 9DU
U.K.

Courier services should be given the room number (Room 2809) in addition to the postal address.

2.2.1 Telephone - The office is staffed on weekdays from 0800 to 1600. The telephone number is:

+44 1865 857644 (direct line)

Voice mail recordings can be left outside office hours and during official holidays.

The **FAX** number is available at all times:

+44 1865 857632

2.2.2 Email - An email mailbox exists at bettina.qp@ouh.nhs.uk

This may be used for all queries **EXCEPT** those of other schemes or organisations of EQA schemes in the UK when the following email should be used.

queries@ukneqas.org.uk

2.2.3 Website - In collaboration with Cytogenetic European Quality Assessment (CEQA) and EuroGentest, UK NEQAS for Clinical Cytogenetics has developed a web based system for registration, electronic submission and transmission of results as well as progress and performance tracking which was launched in Autumn 2007.

The UK NEQAS for Clinical Cytogenetics scheme has a **website** at:

<http://www.ccneqas.org.uk>

and a link to

<http://www.ukneqas.org.uk>

<http://www.ccneqas.org.uk> consists of a public website which gives information such as EQA timetable, contact details, staff and general information about the Scheme

as well as performance criteria and composition of the Steering Committee. To access these documents, use the grey menu bar on the Home page. Once logged in, all registered laboratory participants (maximum 3) can access EQAs and related information, make submissions as well as access the Individual Laboratory Reports (ILR) and summary documents online. The system will also provide a number of certificates (registration, participation, performance) and some statistical information. Only the first and second registered participants can manage their laboratory details – change passwords, address, contact details and add or delete additional users and purchase EQAs.

<http://ukneqas.org.uk> carries general information about the whole UK NEQAS organisation in addition to specific information for UK NEQAS centres and schemes.

2.3 STAFFING

Dr Rosalind Hastings (Clinical Scientist) is the full-time Scheme Organiser (SO) for the Scheme. **Bettina Quellhorst-Pawley** is the Quality Manager (0.5 WTE) and Rod Howell, (Clinical Scientist) is an external scientific advisor employed on an ad hoc basis. All staff are subject to annual appraisal. A member of staff is usually available in the office for consultation or enquiries during the week during office hours. The Scheme has a Deputy Organiser who receives an honorarium of £1,000 per annum

2.3.1 Assessors - The Scheme Organiser is assisted by other colleagues drawn from the ranks of practicing senior clinical cytogeneticists (**for list see Appendix C**). Assessors are normally senior members of the profession (grade 8a and above) with at least FRCPath part 1 and are usually recruited by advertisement. The Steering Committee occasionally appoints assessors with relevant expert knowledge in a specialist area to assist with a new EQA round and these individuals may also be co-opted onto the Steering Committee. Non-UK assessors are chosen from participating laboratories by the Steering Committee and must have 10 years experience in cytogenetics and an appropriate national qualification, if applicable. Assessor appointments are for four years but can be extended for up to two further periods, each

of two years if required for succession planning. Laboratories providing assessors receive an annual £100 payment per EQA which is credited to their invoice. The assessors also receive a £100 payment less tax and National Insurance either as a voucher or through their payroll. In addition, laboratories receive a deduction of £100 per assessor on their UK NEQAS invoice. The assessors are responsible for scrutinising and assessing technical, analytical and interpretive performance in consultation with the Scheme Organiser and Steering Committee Executive (SCE) (**see Section 2.10 & Appendix C**). Any individual wishing to be an assessor should contact the Scheme Organiser who will be pleased to discuss details.

2.4 OVERSIGHT and PROFESSIONAL LINKS

Accountability for the Scheme is set out diagrammatically in **Appendix A**. The Scheme complies with the UK NEQAS code of practice (**Appendix B**).

All EQA providers are required to seek advice from and report to specialist Steering Committees and Advisory Panels, comprising of expert professionals in appropriate areas of laboratory work, representatives of professional bodies and fellow organisers (**Appendix C**).

2.4.1 Steering Committee - The Clinical Cytogenetics Scheme has its own Steering Committee (SC), chaired by Dr Lorraine Gaunt (Manchester) which provides scientific support to the Organiser. (There is a Steering Committee Executive (SCE), comprising of the Chair, Deputy Scheme Organiser, Secretary and a haematology-oncology specialist that oversees any discrepant results). Steering Committee members are normally senior members of the profession (grade 8a and above) with at least FRCPath part 1 and are recruited from the assessors or by advertisement. Appointments of the Steering Committee are initially for four years but can be extended for up to two further periods of two years each.

2.4.2 NQAPP - The Scheme Organiser also reports to the National Quality Assurance Advisory Panel (NQAAP) for Genetics, chaired by Mr Mike Griffiths, which is responsible for monitoring performance standards in UK laboratories.

2.4.3 Professional Links - The Scheme has informal links with other EQA schemes such as the Molecular Genetics Scheme organised by Dr Sandi Deans (Molecular Genetics EQA, Newcastle) with whom the Scheme shares oversight from the Genetics NQAAP. In addition the Clinical Cytogenetics EQA Scheme has links with the European Cytogenetic Scheme - CEQA, National Cytogenetic Schemes, EMQN (European Molecular Quality Network) and the Eurogentest2 Co-ordinated Action Project. The Scheme also has informal links with the ACC (Association of Clinical Cytogenetics), ECA (European Cytogeneticists Association) and ESHG (European Society of Human Genetics).

2.5 ACCREDITATION

The Scheme is currently recognised by the Joint Working Group for Quality Assurance (JWG) according to criteria developed for all EQA providers (**Appendix F**). The Scheme is currently accredited with CPA and was re-inspected in November 2010. Over the next two years the Scheme will transfer the accreditation to ISO17043. Further information about the EQA Standards may be obtained from CPA(UK)Ltd at 21-47 High Street, Feltham, Middlesex, TW13 4UN, Tel: (020) 8917 8400, Fax: (020) 8917 8500 website <http://www.cpa-uk.co.uk>

2.6 SCOPE OF THE SCHEME

2.6.1 Assessments - The Scheme aims to assess the overall quality of diagnostic analysis performed by a laboratory through a combination of retrospective audit, case scenarios, reference material distributions and web-based EQA. The Scheme assesses tissue-specific performance for constitutional and haematology-oncology cases. The constitutional sub-schemes are Amniotic Fluids, Chorionic Villus samples (CVS), Bloods, Solid Tissues, and Molecular Rapid Aneuploidy, Microarrays and Fanconi Anaemia (pilot). The haematology-oncology sub-schemes (acquired abnormalities), involve Myeloid (CML, AML and MDS combined), B or T Lymphoblastic leukaemia/lymphoma (ALL), Tumours, LPD (Lymphoproliferative diseases) and an Adult Neuropathology Pilot EQA. All aspects of the Scheme are under continuous review in collaboration with the UK

NEQAS Steering Committee and suggestions for enhancements to the existing schemes or development of new schemes are welcome.

2.6.2 EQAs offered in 2012 - the following 10 EQAs will be offered: Myeloid Leukaemia (CML/AML/MDS), LPD, B or T Lymphoblastic leukaemia/lymphoma (ALL), Amniotic Fluid, CVS, Bloods (including Urgent Bloods), Microarray and Tumours. There will also be a Molecular Rapid Aneuploidy EQA for prenatal samples run jointly with UK NEQAS for Molecular Genetics and two pilot EQAs: Adult Neuropathology and Fanconi's anaemia.

2.6.3 Performance criteria - These are criteria by which UK and non-UK laboratories are assessed (**see Appendix E**). The criteria can be found on the CCNEQAS website under 'EQA', 'Performance Criteria'. There are separate criteria for constitutional cytogenetics, haematology-oncology cytogenetics, molecular rapid aneuploidy and microarray. All performance criteria have been divided into **two** broad inter-linked categories:

- **Analytical performance:** Scoring of the quality of submitted analyses and written description including ISCN.
- **Interpretative performance:** Scoring of the quality of submitted reports for interpretation of the karyotype, including clinical advice and follow up studies.

The current performance criteria, including the consequences of poor performance, are given in more detail in **Appendix E** and on the <http://www.ccneqas.org.uk> website home page (Select 'EQA' from the grey menu bar link).

All non-UK laboratories are expected to participate in the interpretation part of the EQA. A non compliance will result in poor performance.

2.6.4 National professional standards - Penalties can be given under the performance criteria if professional standards are not adhered to.

- UK laboratories are expected to comply with the current UK professional standards;
- all non-UK laboratories will be scored against the European Guidelines unless the laboratory submits information to show that

their own national standards should apply;

- Local policy will be commented upon if it is not covered by professional guidelines.

2.7 PARTICIPATION

All participants of the UK NEQAS for Clinical Cytogenetics Scheme must agree to abide by the Participants Manual.

Laboratories are required by accreditation standards and OECD guidelines to participate in EQA on a regular basis for all aspects of their diagnostic service.

Laboratories must not use any EQA images or cases for any purpose other than education and training. **It is the responsibility of the participant to be aware of the start and closing dates of the EQAs they are enrolled in** (current timetable can be seen on the website).

2.7.1 Eligibility - UK NEQAS services are designed principally for the UK public and private sector clinical laboratories serving clinicians and patients. Non-UK clinical laboratories, laboratories with purely research or industrial roles, manufacturers of diagnostic instruments and reagents, and other laboratories are also welcome to participate. Manufacturers may do so on a 'technical and analytical' only basis, i.e. receiving samples and returning results. All UK clinical service laboratories must agree to the current JWG conditions of participation (**Appendix F for UK laboratories**). All non-UK clinical service laboratories must agree to the current conditions of participation (**Appendix G for non-UK laboratories**).

2.7.2 Period - Participation in the Scheme is deemed to be continuous with online annual renewal and invoicing for subscription fees for each NHS financial year (1st April to 31st March). Registration may be done at any time during the year, however, enrolment for the year's EQA runs for a limited period at the beginning of the calendar year. Participants are alerted by email once enrolment is open. Participation in EQA begins 1st April although new or late registering laboratories can enrol for the Autumn EQA round after this date.

2.7.3 Charges - Annual subscription charges are based on the full costs of providing EQA services according to the not-for-profit terms of the UK NEQAS code of practice. As such they are subject to

continuous review and may be reduced if surplus is generated. Equally they may be increased if costs rise or if participation decreases. The current tariff of charges is either tissue/disease or technique based

2.7.4 Registration procedure - Registration gathers the full details of the participating laboratory. Once a laboratory's registration has been accepted, the new participant can enrol for specific EQA schemes. This enrolment is renewed every year. As indicated previously, registration may take place at any time.

2.7.5 Registration Fee - There is an annual registration fee of £110 (£160 for non-UK laboratories).

2.7.6 EQA Fees - All EQA charges are placed on the static website in mid January and can be found under 'EQA'. Haematology-oncology EQA incurs a higher workload which is reflected in the higher price. Dry Pilot EQAs are usually free of charge for the first year, there is a charge of £50 for Pilot EQAs involving samples.

2.7.7 VAT - Due to changes in the EU VAT laws in May 2007, all European laboratories, except NHS laboratories located in ENGLAND, must give their VAT number. Hence laboratories in Wales, Scotland, Northern Ireland and non-NHS UK laboratories will be charged VAT. All laboratories outside the EU are VAT exempt.

2.7.8 Refunds - Refunds of subscription charges are only payable under exceptional circumstances.

2.7.9 UK NEQAS laboratory code - On enrolment, each participant is given a unique UK NEQAS laboratory code which remains associated with that participant. Re-allocation of codes and data can occur where laboratories close, merge or split. All codes have the form 80***, where *** is unique to the individual laboratory. **Please use your laboratory code in all correspondence with the Scheme.**

2.7.10 Reporting of validated material - The materials used are independently validated by assessors and/or the Scheme Organiser as specimens suitable for EQA assessment.

2.7.11 Reporting of results of EQA material - All participants are expected to return results promptly within the specified reporting period. Failure to do so may have the consequence of the laboratory receiving

a poor performance designation, (see performance criteria).

2.7.12 Assessment documentation to be completed by laboratories – The type of EQA will determine which documentation is required (see **Appendix D**). EQA instructions on the website will contain details of documentation to be submitted. Some template forms need to be downloaded from the website and completed before uploading. Examples of completed template forms are given in **Appendix D**.

2.7.13 ISCN - All reports will be marked against the current ISCN nomenclature. Since April 2010 this has been ISCN 2009.

2.8 COMMUNICATION with PARTICIPANTS

2.8.1 Annual Report – An annual report is produced at the end of the annual assessment round. A copy of the current document is available on the website under 'Scheme'. The report includes a general overview of the Scheme, summaries of pilot schemes undertaken during the year, plans for next years' assessment etc. Where appropriate the report will also contain a summary of EQA results (see also summary sheets distributed with the individual laboratory report).

2.8.2 Annual Participants' Meeting – There is an annual participants' meeting. All participants are notified of the meeting and agenda in advance. Minutes and an attendance register are taken. This years meeting will take place at the first ACC/CMGS Conference in Birmingham. . The date and time of the meeting will be communicated to participants closer to the date. The PPM meeting will review the EQAs of 2011, discuss, what went well and what can be improved. There will be opportunity for open discussions.

2.8.3 Individual Laboratory Reports (ILRs)
ILRs are the main interface with participants and these are designed to be informative and easy to interpret. Reports share the following features:

- A summary of analytical and interpretative scores;
- Educational comments on the submitted individual reports (some may incur penalties);
- General comments, recommendations and performance status.

In addition to the ILRs, laboratories receive an EQA Report which includes the performance score distributions.

Pilot EQAs usually involve one single case are not usually scored and no performance status is given.

2.8.4 Result validation – Results for a specific EQA distribution should be checked to ensure that they are the ones returned by your laboratory. Mistakes can occur if figures are misinterpreted. The Scheme should be informed immediately so that the necessary corrections can be made and a new report issued.

2.8.5 Amendments after receipt of reports - These should be reported in writing to the Scheme with a full explanation of the reason for any amendment. Problems associated with any errors by UK NEQAS will be amended immediately and a new report generated; there is internal audit of such rare occurrences. **When communicating with the Scheme, laboratories should use their unique laboratory code at all times.**

2.8.6 Participation certificates – Participation and performance certificates are made available online at the end of the Spring and Autumn EQA rounds, once the appeals process is completed. There are separate participation and performance certificates for the Spring and Autumn EQA rounds.

2.8.7 Laboratory Feedback – Occasionally laboratories will be asked to complete online questionnaires when specific information is required by the Scheme Office.

2.8.8 Management Review – The annual Management Review is submitted to the Steering Committee and CPA UK Ltd as part of the internal Quality Management. The review includes participant feedback, a review of the Scheme including poor performance and any complaints.

2.9 MATERIALS

The Scheme receives slides, images (jpeg) fixed cell suspensions and DNA for EQA purposes. All material is provided by a suitable, accredited (e.g. CPA) laboratory providing a diagnostic service. Images from submitted cases are captured by the Scheme Office.

2.10 PERFORMANCE PROBLEMS

2.10.1 Acceptable performance criteria - UK laboratories are subject to performance

surveillance under JWG conditions as defined by the Genetics NQAAP (see **Appendix B**). This Scheme is therefore required to provide information on persistent poor performers to the Genetics NQAAP. Acceptable performance criteria to reflect the needs of a clinical diagnostic service are agreed by the Genetics NQAAP after consultation with the Organiser and ratification by the SC. Special procedures are used to identify those laboratories which have breached these limits on a set number of occasions within the cumulative reporting period. Acceptable performance criteria and action taken on poor performers is described in **Appendix E**. The performance criteria documents can be found the website home page <http://www.cneqas.org.uk/> (Select 'EQA' from the grey menu bar link).

When a persistent poor performance referral is made to NQAAP, the identity of the laboratory will be made known to both the NQAAP and JWG panels.

2.10.2 Non-UK laboratories – Non UK laboratories are not subject to performance surveillance by **NQAAP** but will receive notification of their unsatisfactory performance from the Steering Committee via the Scheme Office.

2.10.3 Poor Performance- This is incurred for the following reasons and applies to UK and non UK laboratories (See performance criteria on website).

- Non-submission;
- Critical analytical error (miss or invent an abnormality)
- Critical interpretation error which affects patient management;
- No interpretation of cytogenetic results.

2.10.4 Disqualification - A laboratory will be disqualified from an EQA if additional information is added to a translated report that is not present in the original report or if participants are found colluding with another participant.

2.11 COMPLAINTS PROCEDURE

Minor misunderstandings or problems with specimens and reports, can usually be resolved over the telephone or by email.

2.11.1 Appeals – Laboratories usually have 15 working days to appeal any penalty points given in their individual laboratory reports. All appeals must be uploaded online within three weeks of release of the Individual Laboratory Report (ILR). An

acknowledgement of their receipt will be sent via email. All appeals are reviewed by assessors and the SC. **Please note the appeals process may take six to eight weeks.** Formal notification of the outcome of the appeal will be given to the laboratory by the Scheme. **Any appeals received after the closing date will not be reviewed.**

2.11.2. Complaints - All formal written complaints are discussed at the SC and the SO will reply to the complainant. The Chair will respond to any complaints sent directly to him/her. The addresses of SC and NQAAP chairs are available in the **Appendix C** for any participants who wish to express comments or concerns about the Scheme and its operation.

2.11.3. Unresolved complaints - If difficulties persist, then participants with continued justified cause for complaint about any aspect of the service should communicate their concerns immediately to the chair of the SC, preferably in writing - though a preliminary telephone call may assist in clarifying the issue and establishing the requisite action.

- Where the complaint is about Scheme logistics, or a matter related to performance assessment and Scheme design, it is more appropriate to contact the Scheme Organiser;
- If the complaint concerns the conduct of the Scheme Organiser, or Quality Manager, then the Directorate Manager – Mr Guy Davies - should be contacted;
- Complaints are logged, and the action taken recorded and audited;
- If the complaint concerns the conduct of the Steering Committee, the Chair of the Steering Committee should be contacted;
- If contacting the SC does not deliver satisfactory results, the NQAAP chair should be contacted;
- If the issue concerns a persistent poor performance designation, the Chair of the NQAAP may also be contacted;
- Where lack of compliance with CPA (UK) standards is suspected by the complainant, the Chief Executive of CPA (UK) may be contacted;
- Where the UK NEQAS code of practice itself is the issue of

Comment [A1]: Are we going to pass this on to national bodies?

concern, the Chair of the UK NEQAS Executive is appropriate.

In all cases, UK NEQAS staff will provide the names and addresses of the appropriate individuals.

2.12 CONFIDENTIALITY

Laboratories must not disclose UK NEQAS participant codes to third parties. Raw data and performance scores are confidential between the individual laboratory and UK NEQAS for Clinical Cytogenetics staff.

Participation information on whether a laboratory participates in UK NEQAS or a specific EQA will be disclosed to accreditation bodies, Orphanet database and other EQA related bodies. The unique laboratory code, raw data or performance will not be disclosed to these bodies. A laboratory can specifically request that the participation information is not disclosed; this request has to be made to the SO in writing.

Performance scores (and some relevant raw data) may be shared with the relevant NQAAP panel under defined circumstances (see **Appendix E**) as part of the routine reporting of persistent poor performance. When a laboratory is referred to NQAAP the identity of the laboratory will be disclosed to the panel. These data, in anonymised form, may be shared with local management, accrediting bodies, and suppliers of equipment and reagents where appropriate and necessary, *but only with the participant's explicit permission*.

UK NEQAS for Clinical Cytogenetics images, reports and documents are copyright and may not be copied, distributed, published or used for publicity and promotion in any form without the written consent of the Scheme Organiser on each and every occasion, though performance data may be shared with individual clients (e.g. GPs, clinicians, pharmaceutical companies) without consultation.

3.0 FEEDBACK on this MANUAL

This Manual has been made as comprehensive as possible, but it is appreciated that revision may be required to reflect changes and / or progress. Participants are invited to make comments

and suggestions, so that amendments may be made for the next edition. This also applies to the websites, where much of the information contained in this manual can be found.

4.0 ACKNOWLEDGEMENTS

The Scheme relies on the hard work and cooperative efforts of a large number of people including local support staff at John Radcliffe Hospital, Oxford, Steering Committee Executive, Deputy SO and assessors. The Scheme Organiser receives considerable professional support from colleagues without whose professional input the Scheme could not function (see **Appendix C**). The continued loyalty of all participants, which has enabled us to develop and expand to meet the challenges of the new EQA environment, is also acknowledged.

5.0 PARTICIPANTS MANUAL copies

This manual is provided free of charge for the individual use of the Scheme participants, other UK NEQAS centres and professional expert groups.

5.1 USER MANUALS

5.1.1 Laboratory User Manual

A User Manual for the Management system is available on the website under 'Manuals and Guides'.

5.1.2 Assessors User Manual

User Manual for the assessors to print submissions and score the reports is available under 'Manuals and Guides'.

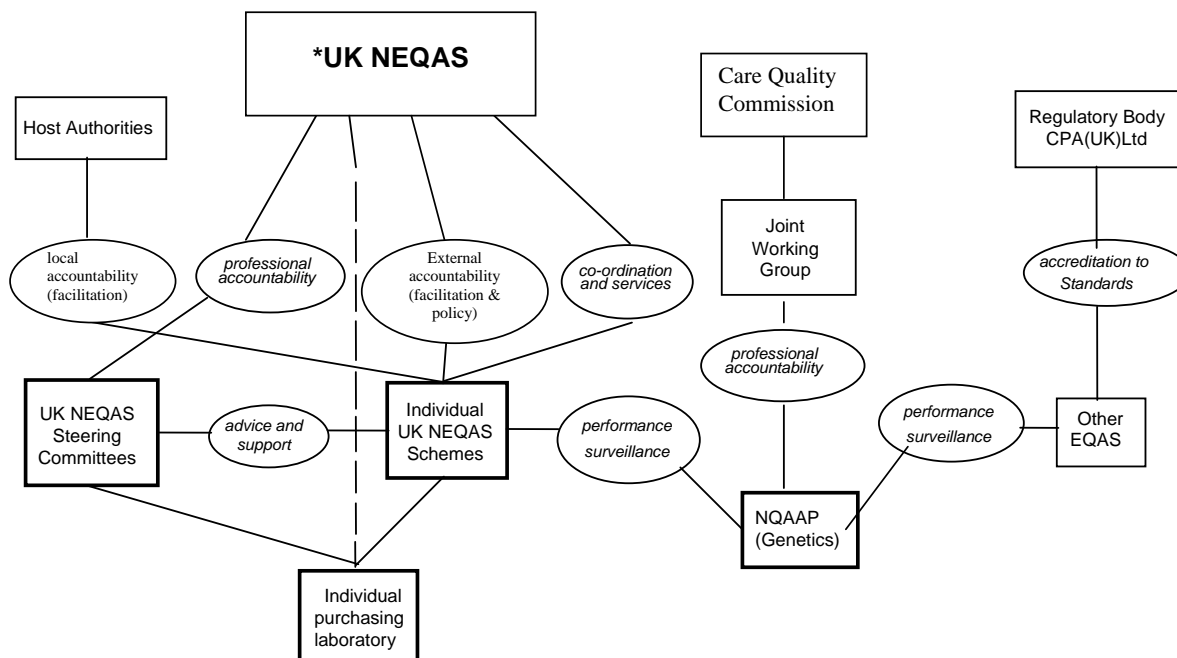
6.0 COPYRIGHT NOTICE.

6.1 UK NEQAS logo – The UK NEQAS logo is copyright. It must not be used by participating laboratories on their documentation. © **Copyright UK NEQAS**

6.2 Participants' Manual - No part of this participant's manual may be copied, distributed or published in any form without the written permission of the Organiser, UK NEQAS in Clinical Cytogenetics, on each and every occasion. © **Copyright UK NEQAS for Clinical Cytogenetics**

Appendix A

Overview of the UK NEQAS Organisation and Advisory Structure



*UK National External Quality Assessment Schemes:

- A charitable company limited by guarantee (charity registration number: 1044013; company registration number: 3012351)
- Company membership (guarantor) open to those Schemes entitled to use the name UK NEQAS
- Executive elected from and by the membership
- UK NEQAS pilot schemes may enjoy associate membership

Appendix B

The UK NEQAS Code of Practice for member schemes

DATED 22 November 2011

1. Defined Terms

1.1 **“Company”** means the legal entity known as United Kingdom National External Quality Assessment Service – a company limited by guarantee and a registered UK Charity.

1.2 **“Executive Committee”** means those directors the company have appointed to perform the duties of the executive committee as defined in the memorandum and articles of the association of the company.

1.3 **“Members”** are defined as EQA Schemes or groups of EQA Schemes which have been accepted for membership of the Company as represented through the members Scheme or Unit Organiser/Director

1.4 **“Organiser”** means the individual designated by the executive committee as being responsible for the design and direction of the member Scheme and accountable to the executive committee for its compliance with the UK NEQAS Code of Practice. The term ‘Director’ may be used by member Schemes to mean Organiser if this is their tradition, provided that there is no confusion in understanding. For example, the distinction must be clear between the Director (head of service) of a department which hosts a Scheme, and the designated Director (= Organiser) of the member Scheme, if they are separate individuals.

1.5 The Executive Committee is accountable to the members for implementation of the strategy for member schemes, as agreed by the members at General Meetings.

1.6 Directors of the Executive Committee are responsible for complying with all UK Company Law and UK Charity Law, as both directors and trustees of the Company.

1.7 Scheme Participants may be individuals, laboratories or other service providers.

1.8 The Executive Committee directors are responsible for ensuring that all Members of the Company adhere and comply with this Codes of Practice, and any other Rules as made by the Executive Committee from time to time in accordance with article 35 of the articles of association and the memorandum and articles of association of the Company.

1.9 This Code of Practice applies to all Members. Entry into Membership of the Company is conditional upon the complete and absolute adherence to these codes and any other subsequent Rules made by the Company.

2. Purpose of the Code

2.1 This Code of Practice governs the behaviour of and provides guidance to Members, the Company, and Directors on the Executive Committee as to best practice and standards and governs the conduct of behaviour between the parties.

2.2 This code operates and is applicable in relation to Members, the Executive Committee, and EQA Schemes.

2.3 In examining an individual’s or Member’s behaviour against this Code, account shall also be taken of the company’s articles and memorandum of association.

2.4 This Code should be read in conjunction with guidance issued from Companies House and the Charity Commission that covers the statutory responsibilities of the directors on the executive committee as company directors and charity trustees.

2.5 All Members shall receive a copy of this Code and the articles of the company upon admission as a Member of the Company.

2.6 An undertaking to abide by this Code is mandatory to all members, Scheme Organisers and Directors on the Executive Committee. It operates as a contract between the Company and its members.

2.7 This Code may be reviewed, to ensure its effectiveness; and compatibility with the ethos of the Company and symmetry, adherence and compatibility to the company’s memorandum and articles of association.

3. Membership Procedures

3.1 Schemes shall be admitted to membership of the Company when approved by the Executive Committee in accordance with the articles of association of the Company.

3.2 Applications for membership shall be made to the Executive Committee on an approved application form available from the Company Secretary and submitted in accordance with the articles of association. The application shall be accompanied by a signed statement from the Organiser that the Scheme(s) complies with the Code of Practice.

3.3 Pilot Schemes intended to become member Schemes shall be admitted to Associate membership in accordance with the memorandum and articles of association and will comply with all relevant conditions of this Code of Practice, including clause 6.3 where a subscription is charged.

3.4 The Executive Committee can in its absolute discretion decline to admit to Membership any Applicant that fails to fulfil the criteria for the objects of the memorandum and articles of association, and this Code of Practice.

3.5 Only those Schemes that are admitted to full or associate membership of the Company by the Executive Committee shall be entitled to use the service mark "UK NEQAS" and associated logo.

3.6 A Scheme that fails to comply with this Code of Practice shall be reminded by the Executive Committee of its obligation as a member of the Company and be required to rectify the non-compliance. In the event that a Scheme still fails to comply with this Code of Practice, the Executive Committee will prepare a written case for that Scheme to cease to be a member of the Company, and be entitled to follow the procedure with regard to the termination of membership as detailed at article 6 of the Companies articles of association.

3.7 For a breach by a Member of this Code of Practice the Member shall be offered three months in which to prepare a written case for remaining as a member of the Company. The documents shall be circulated to all members, who will determine, by a majority vote of the Company in General Meeting, whether the member should be expelled from the Company, provided that any member to be so expelled shall also have the opportunity to make representation to the meeting at which the decision is to be made, in accordance with article 6 of the Company's articles of association.

3.8 Any decision to expel a member shall have immediate effect. Membership is not transferable, and all such rights and privileges shall cease upon the Member ceasing to be such.

3.9 A Member or Scheme Organiser will be declined and expelled from Membership if it carries out activities of a profit-making nature which includes, but is not limited to declaring a dividend, bonus or otherwise making profit. Any operating surplus will be reinvested.

4. Member Scheme Management

4.1. The Scheme shall be open to all UK providers offering a clinical service for investigations covered by the Scheme. Other participants may be accepted by agreement with the Scheme Organiser.

4.2. The investigations covered by the Scheme shall be selected on the basis of their clinical relevance.

4.3. Schemes shall be independent of any manufacturing and marketing interests in equipment and reagents in the field in which they operate, and any interests in the provision of analytical or other services shall be declared.

4.4. The staff involved in directing and operating the Scheme shall be appropriately qualified to the required professional standard and proof of such qualifications should be provided.

4.5. The conditions of participation for UK providers of direct or indirect clinical service shall be those currently defined by the Joint Working Group for Quality Assurance.

4.6. The Scheme Organiser shall liaise with a UK NEQAS Steering Committee and/or Specialist Advisory Group comprising appropriate experts, participants and clinical advisers approved by the Executive Committee.

4.7. Minutes and lists of attendees at Steering Committee/Specialist Advisory Group Meetings shall be copied to the Company's office.

4.8. The Scheme Organiser shall monitor those participants failing to maintain acceptable levels of performance. The Scheme Organiser shall be responsible for presenting reports as required to the appropriate division's National Quality Assurance Advisory Panel (NQAAP) which is recognised by the Joint Working Group for Quality Assurance.

4.9. The full, realistically calculated costs of operating the Scheme shall be fully recovered from participants' subscriptions.

4.10. Schemes shall be non profit making and in no circumstances shall operate on a profit making basis to benefit individuals, shareholders, guarantors or host organisations. Any operating surplus shall be reinvested in the Schemes and applied in accordance with the Company's memorandum and articles of association.

4.11. The Scheme Organiser shall ensure that all Schemes comply with this Code of Practice and the Memorandum and Articles of Association including reporting any profit making activity to the Executive Committee.

4.12. Management arrangements shall enable continuity of the EQA service to participants.
UK NEQAS Code of Practice final 17.11.11

5. Member Scheme Design

5.1. The Scheme's aim shall be to promote optimal patient care by facilitating the availability of reliable laboratory investigations, through provision of objective information on participant performance and professional advice and assistance where appropriate.

5.2. Schemes shall enable the detection of inadequate performance by participants. Participants with apparent performance difficulties should be encouraged to improve by education rather than penalty.

5.3. Material for investigation shall be distributed regularly at an appropriate frequency and in appropriate numbers, guided by advice from Steering Committee or Specialist Advisory Group.

5.4. Evidence shall be available to demonstrate the appropriateness, stability and uniformity (homogeneity) of the material distributed.

5.5. The Scheme shall provide rapid turnaround of results and performance data to participants.

5.6. Target results should be identified and an appropriate (usually quantitative) evaluation of results be presented to allow comparison of individual participants' results with overall results.

5.7. The Scheme shall conform to relevant safety standards and transport regulations.

5.8. Confidentiality of individual participants' results and performance data shall be maintained except under circumstances specified in the Joint Working Group for Quality Assurance Conditions of Participation for UK clinical laboratories.

6. Obligations and Responsibilities of Member Schemes and their Scheme Organisers

6.1. Scheme Organisers shall keep the Company informed of changes in Schemes' details and activities and a Register of all members shall be kept at the Company's registered office in accordance with the Articles.

6.2. Scheme Organisers will have reporting and filing duties which shall include the completion of an Annual Return and mid year update as required. Changes to scheme details and other information for publication (eg enhancement of services and notice of participants meetings) shall be made promptly to the Company and these amendments checked by Schemes after publication.

6.3. Financial returns including annual accounts shall be submitted as required to the Executive Committee. These shall be in a standard format and validated by appropriate supporting documentation indicating agreement and acknowledgement by the budget holder. Scheme Organisers shall disclose all sources of UK NEQAS Scheme incomes. In addition, any additional income which supports the viability of the Scheme shall also be stated.

6.4. The Scheme shall share a common participant identification code with other UK NEQASs and co-operate fully with the development and maintenance of the unified participant identification code database. Information in the data base shall not be used by member schemes to the detriment of other member schemes.

6.5. The Scheme shall contribute to the operating costs of the Company's Office and the costs of the services provided by the Office, as determined by the Association and determined by the Executive Committee.

6.6. The Scheme Organiser shall uphold, support and promote the underlying principles of the Company as embodied in the memorandum, articles of association, Code of Practice and Rules agreed by the Members at Annual General Meetings and Conferences. Scheme Organisers shall play a full part in ensuring that the Company is a harmonised, participant-responsible service and shall not damage the reputation of the Company as a whole through inappropriate action or inaction.

6.7. Scheme Organisers shall achieve appropriate accreditation for their Schemes.

6.8. All aspects of the work of a member Scheme shall be open to audit conducted by or on behalf of the Company. The purpose of any such audit shall be to assess the management of the Scheme in its ability to provide a service that complies with the stated aims as stated in the memorandum, articles of association and Code of Practice of the Company.

6.9. Where Organisers of member Schemes also operate other services including non-member Schemes, other than pilot Schemes intended to become member Schemes, the other services shall be financially independent of the member schemes.

6.10. Organisers and staff of member Schemes and members of Steering Committees or Specialist Advisory Groups shall neither operate nor advise any EQA schemes which are in competition with member Schemes.

6.11 In the event of a scheme developed/provided as a collaboration between two or more members/divisions, results data for all participants will be combined and presented to participants, as a minimum on an annual basis. Combined performance data will be presented to the relevant National Quality Assurance Advisory Panel(s).

6.12 The Organiser of the Scheme shall ensure that the Scheme is carried out in a non profit making capacity and shall communicate this ethos across all stakeholders of the Scheme

6.13 The Organiser of the Scheme shall ensure that all Members of their Scheme are aware that they can be expelled from membership of the Company if they operate the Scheme in a profit making manner.

Appendix C

Assessors, membership of Steering Committee and National Quality Advisory Assurance Panel For Genetics 2012

UK NEQAS for Clinical Cytogenetics: Deputy Organiser and Scheme Assessors

Constitutional Scheme	Location	Start of term of Office
Mr Eddy Maher (deputy SO)	Edinburgh	2003
Miss Kath Smith	Sheffield	2004
Mrs Carolyn Campbell	Oxford	2005
Mr Graham Fews	Birmingham	2006
Dr Ron Hochstenbach	Utrecht, Holland	2007
Dr Heleen Schuring	Utrecht, Holland	2008
Dr Nicole de Leeuw	Nijmegen, Holland	2008
Mrs Sian Morgan	Cardiff	2009
Dr Eric Sistermans,	Amsterdam, Holland	2009
Dr Ingrid Simonic	Cambridge	2010
Dr Kathy Mann	Guys, London	2010
Mr Richard Hall	Guys, London	2010
Mrs Heather Ward	Manchester	2010
Mr Jerome Evans	Newcastle	2010
Mr David Delmege	Bristol	2010
Haematology-oncology Scheme	Location	Start of term of Office
Mr Dom McMullen	Birmingham	2003
Mrs Sarah Ryley	Harrow, London	2004
Mrs Polly Talley	Sheffield	2004
Dr Sheila O'Connor	Leeds	2005
Dr Nick Bown	Newcastle	2005
Mrs Kate Martin	Nottingham	2010
Dr Manuel Teixeira	Porto, Portugal	2006
Mrs Sandra Birdsall	Cardiff	2006
Mr David Betts	Dublin, Eire	2008
Ms Markella Mikkelsen	Athens, Greece	2009
Mrs Marianne Grantham	Barts, London	2011
Mr Steve Chatters	GOS Haem, London	2011
Mrs Amy Logan	Belfast	2011
Ms Nicola Foot	Guys, London	2011
Mrs Caroline Devlin	Glasgow	2011

Assessors' term of office is 4 years with the option to extend for a further 4 years.

Scheme Organiser is involved in all EQA rounds

Sarah Ryley has served six years as assessor and on the Steering Committee. The Scheme would like to thank her for all her help, time and support.

UK NEQAS Steering Committee for Clinical Cytogenetics

Name	Role	Affiliation	Term of Office
Dr Ros Hastings	*Scheme Organiser (SO)		n/a
Mr Eddy Maher	*Deputy SO		2002
Mrs Carolyn Campbell		PS & RCPATH	2005
Mr Graham Fewes	*Secretary		2011
Dr Lorraine Gaunt	*Chair		2006
Prof Andrew Green		CGS	2006
Dr Sandi Deans		UK NEQAS MG	n/a
Dr Sheila O'Connor		BSH	2008
Dr Mike Griffiths	Observer	NQAAP	n/a
Mrs Sandra Birdsall			2009
Mrs Kate Martin			2010
Dr Ingrid Simonic			2010
Dr Nick Bown	*Haematology-oncology specialist	UKCCG	2010
Dr Nicole de Leeuw			2011
Dr Heleen Schuring-Blom			2011

* Steering Committee Executive

National Quality Assurance Advisory Panel (NQAAP) for Genetics

Name	Role	Affiliation	Term of Office
Mr Mike Griffiths	Chair	JWG	2011
Ms Roberta Goodall		ACB	2005
Dr Ann Curtis		CMGS	2006
Dr Dr Dave Robinson		CMGS	2006
Dr Nick Cross		BSH	2007
Ms Fiona Coyns		AGT	2007
Mrs Kim Smith		ACC	2010
T.B.C.		ACC	2010
Dr Sandi Deans	By invitation	Molecular Genetics Scheme Organiser	n/a
Dr Ros Hastings	By invitation	Clinical Cytogenetics Scheme Organiser	n/a
Dr Simon Patton	By invitation		
Dr Jane Moorhead	By invitation		
Mr Jordan Clark	By invitation		
Prof John Reilley	By invitation		
Ms Jane Holden	By invitation		
Mr Paul Griffiths	By invitation		

n/a – not applicable

Address Steering Committee Chair:

Dr Lorraine Gaunt
Regional Cytogenetics Unit - Genetic Medicine (6th Floor)
St Mary's Hospital
Oxford Road
Manchester
M13 9WL

Address NQAAP Chair:

Mr Mike Griffiths
Regional Genetics Laboratory
Women's Hospital
Edgbaston
Birmingham
B15 2TG

Appendix D

Clinical Cytogenetics covered by the Scheme

The following tissues, diseases and techniques are covered by the Scheme:

Constitutional

- Amniotic Fluid
- CVS
- Bloods (incl. urgent referral)
- Solid Tissues
- Fanconi Anaemia (Pilot)

Haematology-oncology

- Myeloid (AML, CML, MDS)
- B or T lymphoblastic leukaemia/lymphoma (ALL)
- Lymphoproliferative disease
- Solid Tumours
- Adult Neuropathology

Technique Based EQA

- Molecular Rapid Aneuploidy Testing (QF-PCR & MLPA)
- Microarray

The following types of EQA may be involved:-

1. **Retrospective reports** involve the submission of two cytogenetic reports for assessment by assessors (analytical and interpretive proficiency assessed. N.B. No slides, analytical proficiency is restricted to ISCN and written description). If the interpretation is done separately by the clinician then a copy of their report needs to be submitted.
2. **Case scenarios** involve the interpretation and reporting of two case scenarios. The case scenarios give the referral details and the results of the analysis (analytical and interpretive proficiency assessed. N.B. Analytical proficiency is restricted to ISCN and written description).
3. **On-line EQA** involves the online analysis and interpretation of two or three cases. The online EQA enables you to select appropriate additional tests (e.g. FISH) if required for the reporting of the case (analytical and interpretive proficiency assessed).
4. **Validated samples** involves the distribution of DNA or cell suspension samples for analysis and interpretation of two or three cases (technical, analytical and interpretive proficiency assessed)

Documents required for each EQA type.

All documentation must be anonymised with patient, laboratory and staff names obscured. If the original report was not in English please submit a copy of the original report and an English translation.

1. **Retrospective reports:-** Copy of cytogenetic report (including translation if original not in English). Online documentation also to be completed.
2. **Case scenarios:-** No documentation - only online documentation to be completed.
3. **Online EQA:-** No documentation - only online documentation to be completed.
4. **DNA:-** No documentation - only online documentation to be completed.

Example completed templates

The following completed templates are given:-

1. **Retrospective reports:-**
EQA Case Submission Form (p20) – select the sex (male/female/unknown) in section A. The unique laboratory ID needs to be entered for each case. If no preliminary result but the FISH is reported at the same time as the G-banded analysis, please put the FISH analysis under Preliminary Results (section C) and make a comment under ‘Laboratory comments’ in section B.
2. **Case scenarios:-**
EQA Case Scenario Assessment Form (p21) – select the case scenario (A/B) in section A.
3. **Online EQA:-**
No template required.
4. **Validated samples:-**
No template has been required for the MRA or LPD schemes since 2010.

Laboratory No.	80000
EQA	MDS Scheme
Year	2007 Autumn

RETROSPECTIVE

EQA-Case Submission Form

Fill in this form with details of the cases you are submitting to the EQA. Use one form for each case submitted.

A. Referral details

Case Number:	07/452	Date of Birth:	01/01/2008	Sex:	Unknown
Sample Type:	Bone Marrow	Date Received:	31/12/2007	Days to report:	10
Referral Reason:	Give the referral reason e.g. ? AML, Auer rods present.				
Additional Information:	Information acquired after receiving sample but prior to reporting e.g. AML diagnosis confirmed.				

B. Results

Your Results:	46,XX TEL/AML1 rearrangement detected by FISH. (i.e. ISCN and/or a summary statement but no other text)
Laboratory Comments: (include details of probe(s) or primers used)	Any additional studies that you would undertake to confirm this result (if applicable) or as a result of subsequent information received (specify the nature of this information). If the submitted case was entered in a European trial, state which FISH tests were required. Any local policies that determine the content of the cytogenetic report. Any additional information you need to relay to the assessors.

C. How you obtained the results

	Preliminary result (if applicable)	Final result
Total No. of metaphases/interphases examined	100	20
No. of cells counted, scored or partially analysed		10
No. of metaphases fully analysed		10
Banding Quality Score		2

D. Method used (preliminary result obtained through)

FISH:	<input checked="" type="checkbox"/>	QF- PCR:	<input type="checkbox"/>	RT-PCR:	<input type="checkbox"/>	MLPA:	<input type="checkbox"/>	Chromosome analysis:	<input checked="" type="checkbox"/>
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Laboratory No.	80000
Scheme	Amniotic Fluid Case Scenario 2007
Year	2007 Autumn

PROSPECTIVE

EQA Case Scenario Assessment Form

On this form enter your report for the specific case scenario. Use a separate form for each case.

A. Result	
Case scenario	1 (Use the arrow to select Case 1 or 2)
Your Result:	46,XX Di George deletion detected. (i.e. enter only the ISCN and/or a summary statement, no other text)

B. Report
Write your Cytogenetic report in this box. This should include: Patient details Written description of cytogenetic result Interpretation of result Any onward referral required Any riders that would normally given on your reports

C. Additional comments
Any additional studies that you would undertake to confirm this result (if applicable) PRIOR to reporting. This is to explain any local policies that determine the content of the report. Any additional information you wish to relay to the assessors.

Appendix E

Performance Standards for the Scheme

Constitutional Scheme and Haematology-oncology Scheme and MRA and Microarray

Background to Performance Scoring in Cytogenetics

Laboratory performance surveillance and assessment by the UK NEQAS for Clinical Cytogenetics Scheme is regarded by the profession as an essential component of quality assurance of the clinical cytogenetics service in the UK. External quality assessment facilitates optimal patient care by encouraging the availability of timely and reliable laboratory investigations and professional advice.

The cytogenetics scheme maintains the principle of assessment by professional consensus, and supports the general philosophy of the UK NEQAS schemes to improve standards by education and peer group review rather than by penalty wherever possible. Performance criteria provide benchmarks which allow comparison of laboratories against national guidelines. Satisfactory performance reassures clinical colleagues, other professionals, and the public about the standard of work in laboratories.

In order to comply with CPA and UKAS accreditation standards for External Quality Assessment Schemes (ILAC 43/ISO 17043 standards), it is necessary to define the criteria for acceptable performance. The UK NEQAS Clinical Cytogenetics Scheme has developed a scoring system such that substandard performance in any criterion can be converted into a numerical score. This is considered essential to allow objective comparisons to be made between participant laboratories and against absolute standards. Furthermore, in order to protect the interests of patients, appropriate strategies for dealing with poor performance have to be clearly defined.

A laboratory with persistent poor performance, as defined in the performance scoring document, will be referred to the National Quality Assurance Advisory Panel (NQAAP), which has executive responsibility for maintaining satisfactory standards of work in clinical cytogenetics laboratories in the UK. Such a referral, for any aspect of its service, could have adverse implications for a laboratory for CPA Accreditation. It is clearly important, therefore, that only those laboratories consistently providing an unacceptably low standard of service are identified as being persistent poor performers.

Past performance of UK cytogenetics laboratories would suggest that the referral of a laboratory to NQAAP will be a relatively infrequent event.

Non-UK laboratories with persistent poor performance, as defined in the performance scoring document, will be ratified by the Steering Committee. As there is no European or International Quality Assurance Advisory Panel, no referral can be currently made. It is however, the responsibility of the non-UK laboratory to inform the relevant authorities of a persistent poor performance designation.

The performance criteria for both Schemes can be found on the website (<http://www.ccneqas.org.uk/>) under 'EQA'.

V6 12/2/08

Appendix F

Joint Working Group (JWG) Conditions of Participation by UK Clinical Laboratories in External Quality Assessment Schemes

CONDITIONS OF PARTICIPATION BY UK CLINICAL LABORATORIES IN EXTERNAL QUALITY ASSESSMENT SCHEMES

Joint Working Group for Quality Assurance : Conditions of EQA Scheme Participation

The Joint Working Group for Quality Assurance (JWG) is a multidisciplinary group accountable to the Royal College of Pathologists for the oversight of performance in external quality assurance schemes (EQA) in the UK. Membership consists of the Chairmen of the National Quality Assurance Advisory Panels (NQAAPs), and representatives from the Institute of Biomedical Sciences, the Independent Healthcare Sector, the Department of Health and CPA (UK) Ltd.

1. The Head of a laboratory is responsible for registering the laboratory with an appropriate accredited EQA scheme.
2. The laboratory should be registered with available EQA schemes to cover all the tests that the laboratory performs as a clinical service.
3. EQA samples must be treated in exactly the same way as clinical samples. If this is not possible because of the use of non-routine material for the EQA (such as photographs) they should still be given as near to routine treatment as possible.
4. Changes in the test methodology of the laboratory should be notified in writing to the appropriate Scheme Organiser and should be reflected in the EQA schemes with which the laboratory is registered.
5. Samples, reports and routine correspondence may be addressed to a named deputy, but correspondence from Organisers and NQAAPs concerning persistent poor performance (red – see point 8.) will be sent directly to the Head of the laboratory or, in the case of the independent healthcare sector, the Hospital Executive Director.
6. The EQA code number and name of the laboratory and the assessment of individual laboratory performance are confidential to the participant and will not be released by Scheme Organisers without the written permission of the Head of the laboratory to any third party other than the Chairman and members of the appropriate NQAAP and the Chairman and members of the JWG. The identity of a participant (name of laboratory and Head of Department) and the tests and EQA schemes for which that laboratory is registered (but not details of performance) may also be released by the Scheme Organiser on request to the Health Authority, Hospital Trust/Private Company in which the laboratory is situated after a written request has been received.

7. NQAAP may, with the written permission of the Head of a laboratory, correspond with the Authority responsible for the laboratory, about deficiencies in staff or equipment which, in the opinion of the NQAAP members, prevent the laboratory from maintaining a satisfactory standard.
8. Laboratories' EQA performance will be graded using a traffic light system; green will indicate no concerns, amber poor performance, red persistent poor performance, with black being reserved for the tiny number of cases that cannot be managed by the Organiser or NQAAP and that have to be referred to the JWG. The criteria for poor performance (amber) and persistent poor performance (red) are proposed by the EQA scheme Steering Committee in consultation with the EQA Provider/Scheme Organiser and approved by the relevant NQAAP.
9. When a laboratory shows poor (amber) performance the Organiser will generally make contact with the participant in accordance with the Scheme Standard Operating Procedure for poor performance. Within 2 weeks of a laboratory being identified as a persistent poor performer (red), the Organiser will notify the Chairman of the appropriate NQAAP together with a resume of remedial action taken or proposed. The identity of a persistently poor performing laboratory (red) will be made available to members of the NQAAP and JWG. 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 may be arranged.
10. If persistent poor performance remains unresolved (black), 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.
11. Problems relating to EQA Schemes, including complaints from participating laboratories, which cannot be resolved by the appropriate Organiser, Steering Committee or NQAAP, will be referred to the Chairman of the JWG.

Joint Working Group for Quality Assurance in Pathology, August 2010.

Appendix G
UK NEQAS for Clinical Cytogenetics
Conditions of Participation
by
non-UK Clinical Laboratories
in
External Quality Assessment Schemes

CONDITIONS OF PARTICIPATION

1. The Head of the laboratory will be responsible for registering the laboratory with the Organiser as a participant in the appropriate EQA Schemes (EQAS) and must indicate which of the tests available within the Scheme the laboratory performs and for which it should be registered.
2. The laboratory should be registered with available EQA schemes to cover all the tests that the laboratory performs as a clinical service. Any changes in the laboratory's requirements in this respect must be notified in writing to the Scheme Organiser.
3. Samples, reports and routine correspondence may be addressed to a named Deputy, but correspondence from Scheme Organiser and Steering Committee concerning poor performance or unsatisfactory return rates, will be sent directly to the Primary contact i.e. Head of the laboratory.
4. EQA samples must be treated in the same way as clinical samples. If this is not possible because of the use of non-routine material for the EQA (such as photographs) they should still be given as near to routine treatment as possible.
5. Changes in the test methodology of the laboratory should be notified in writing to the appropriate Scheme Organiser and should be reflected in the EQA schemes with which the laboratory is registered.
6. The EQA code number of the laboratory and the assessment of individual performance is confidential to the participant and will not be released by Scheme Organiser to any third party, *other than* the Chairman and members of the Steering Committee and in specified circumstances the Chairman of the accrediting body, without the written permission of the Head of the laboratory. The identity of a participant (name of laboratory and Head of Department) and the tests and EQA schemes for which that laboratory is registered (but *not* details of performance) may also be released by the Scheme Organiser on request to the Health Authority, Hospital Trust/Private Company in which the laboratory is situated after a written request has been received. (see section 2.12).
7. This Scheme has criteria for unsatisfactory performance agreed by the Genetics NQAAP (UK National Quality Assurance Advisory Panel). When a laboratory shows unsatisfactory performance or fails to return results, the Organiser will generally make informal contact with the participant. If performance fails to improve, the Organiser will notify the Chairman of the Steering Committee. Advice is then offered to the Head of the laboratory by contact in writing.
8. Problems relating to EQA Schemes, including complaints from participating laboratories, which cannot be resolved by the appropriate Organiser or Steering Committee will be referred to UK NEQAS executive.
9. All reports, and the data they contain, issued by the EQA Organiser are copyright and may not be published in any form without the permission of the appropriate Steering Committee.