



**NATIONAL EXTERNAL QUALITY
ASSESSMENT SCHEME
IN
CLINICAL CYTOGENETICS**

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PARTICIPANTS' MANUAL 2010

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.

UK NEQAS aims to:-

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

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 Radcliffe Hospital Trust.

UK NEQAS for Clinical Cytogenetics is administered through the Directorate of Laboratory Medicine and Clinical Sciences 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 Radcliffe Hospitals NHS Trust. The Scheme Organiser is the budget holder for the Scheme and obtains advice

and support from Mr Nigel Byng (Finance Manager).

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.

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

An **email** mailbox exists at

ros.hastings@orh.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

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 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. 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, 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 for the Scheme. **Bettina Quellhorst-Pawley** is the Quality Manager (0.5 WTE) and Rod Howell, (Clinical Scientist) is an external scientific advisor. All staff are subject to annual appraisal. A member of staff is usually available in the office for consultation or enquiries during the week. The Scheme buys IT support from the Trust and also pays an annual ‘hotel charge’ which covers other service costs.

The Scheme Organiser is assisted by other colleagues drawn from the ranks of practicing senior clinical cytogeneticists (**for personnel see Appendix C**). Steering Committee members as well as 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 appoint assessors with relevant expert experience 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. Steering Committee and 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. The assessors and their associated laboratory both receive either an annual £100 payment per EQA or £150 per slide distribution EQA. The assessors receive this payment less tax and National Insurance through their payroll. Laboratories receive a deduction in the UK NEQAS invoice. The Scheme has a Deputy Organiser who receives an honorarium of £1,000 per annum. The assessors are responsible for scrutinising and assessing technical,

analytical and interpretive performance in consultation with the Scheme Organiser and Steering Committee Executive (SGE) (**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**). The Clinical Cytogenetics Scheme has its own Steering Committee (SC), chaired by Dr Lorraine Gaunt (Manchester) which advises and provides support to the Organiser. The Steering Committee Executive (SCE), comprising of the Chair, Deputy Scheme Organiser, Secretary and an oncology specialist, oversees any discrepant results. The Scheme Organiser also reports to the National Quality Assurance Advisory Panel (NQAAP) for Genetics, chaired by Dr Roger Mountford, which is responsible for monitoring performance standards in UK laboratories. 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 (see also Complaints Procedures **Section 2.11**).

The Scheme has informal links with other schemes (**see Section 2.1**) and with 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 and Eurogentest.

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 2008. The EQA schemes are accredited to the ILAC 43 standard. Further information about the EQA Standards may be obtained from CPA(UK)Ltd at 45 Rutland Park, Botanical Gardens, Sheffield S10 2PB, tel 0114 251 5800, fax 0114 251 5801, 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 oncology cases. The constitutional sub-schemes are Amniotic Fluids, Chorionic Villus samples (CVS), Bloods, Urgent Bloods, Solid Tissues, and Molecular Rapid Aneuploidy, Microarrays (pilot) and Fanconi's anaemia (pilot). The oncology sub-schemes (acquired abnormalities), involve ALL, CML, AML, MDS, Solid Tumours, and Lymphoma & Lymphoproliferative Diseases (LPD). 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 2010-In 2010 the following EQAs will be offered: AML, ALL, Amniotic Fluid, Bloods, CML, CVS, Lymphoma & LPD, Solid Tissues, Solid Tumours and Urgent bloods. There will also be a Molecular Rapid Aneuploidy EQA for prenatal samples run jointly with UK NEQAS for Molecular Genetics and two pilot EQAs: Microarrays 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 “Performance Criteria”. There are separate criteria for constitutional and oncology cytogenetics. 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 UK NEQAS website under ‘scheme.’ <http://www.ccneqas.org.uk>

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;
- European laboratories will be scored against the European guidelines unless the laboratory submits information to show that their own national standards should apply;
- Non-European laboratories will be scored against UK standards, unless the laboratory submits information to show that their own national standards should apply.

2.7 PARTICIPATION

All participants of the UK NEQAS for Clinical Cytogenetics Scheme must agree to abide by the Participants Manual. Laboratories must not use any EQA images or cases for any purpose other than education and training.

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 an '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, 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 begin at any time during the year. 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 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 above, registration may take place at any time. There is an annual registration fee of £100 (£150 for non-UK laboratories). Due to changes in the EU VAT laws in May 2007, all European laboratories and except those 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.

2.7.4 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 demerge. All codes have the form 80***, where *** is unique to the individual laboratory. **Please use your laboratory code in all correspondence with the Scheme.**

2.7.5 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, though any such increase must be justified to the UK NEQAS for Clinical Cytogenetics S.C. before implementation. The current tariff of charges is either tissue/disease or technique based.

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

2.7.7 Use of reference material - The materials distributed are provided as specimens for the sole purpose of enabling external quality assessment at the recipient's laboratory during the current distribution. All reference slides **MUST** be returned to the Scheme undamaged. **Slides must be**

sent in appropriate containers, with the lids sealed with tape and marked with the unique laboratory number, within a padded envelope. When sending slides from outside the UK, a courier must be used unless previously agreed otherwise with the Scheme Office.

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

2.7.9 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).

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

2.7.11 ISCN - All reports will be marked against the current ISCN nomenclature, ISCN 2009 after April 2010.

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 upon request. 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 which, in the past, has been held at the ACC Spring Scientific Meeting at the end of March/April. In 2007 the format of the participant meeting changed to a dedicated one day meeting involving presentations, workshops and an opportunity for feedback from participants. All participants are notified of the meeting and agenda in advance. Minutes and an attendance register are taken. It was agreed at the 2008 Participants' Meeting (PPM) to alternate the

format between a one day meeting and a shorter slot as part of the ACC Spring Conference. This years meeting will be a full day meeting. Date and venue will be communicated to participants in due course.

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;
- Sample type technical performance (slide quality) if applicable;
- Comments on the submitted individual reports, some incurring penalties;
- General comments, recommendations and performance status.

In addition to the ILRs, laboratories receive a summary letter which includes the performance score distributions. Pilot EQAs are not given scores and a performance status.

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/or performance certificates will be available online. Separate participation and performance certificates will be available at the end of the Spring and Autumn EQA rounds, when the appeals process is completed.

2.8.7 Laboratory Feedback – Feedback questionnaires are available online after the Spring and Autumn EQA rounds respectively. These forms give laboratories an opportunity to feedback to the Scheme on what went well and also with suggestions

for further improvements. Occasionally laboratories will be notified of additional questionnaires online when specific information is required.

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

2.9.1 Sources of slides – To be obtained from a suitable accredited (e.g. CPA) laboratory providing a diagnostic service.

2.9.2 Sources of fixed cells/DNA – To be obtained from a suitable accredited (e.g. CPA) laboratory providing a diagnostic service.

2.9.3 Sources of images– Jpeg images are obtained from a suitable accredited (e.g. CPA) laboratory providing a diagnostic service.

2.9.4 Safety – Please note that participating laboratories are responsible for the safe packaging of slides sent to the Scheme. **UK NEQAS samples should be packaged, dispatched and handled as for clinical specimens. If applicable, appropriate procedures should be used to minimise contact with samples and for their disposal.**

2.9.5 Postage – Distributed reference material may include diagnostic cases and all such **EQA specimens must be in slide boxes sealed with tape and marked with the unique laboratory number, appropriately packaged in a padded envelope and, within the UK, must be sent by registered or special delivery (non-UK by courier) to the Scheme Office to ensure against loss.**

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. Non UK laboratories are NOT subject to performance surveillance by NQAAP. Acceptable performance criteria to reflect the needs of a clinical diagnostic

service are agreed by the 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 on the website under 'scheme' <http://www.cneqas.org.uk/> When a persistent poor performance referral is made to NQAAP, the identity of the laboratory will be made known to the NQAAP and JWG panels.

Non-UK laboratories are not subject to performance surveillance by NQAAP.

2.10.2 Poor Performance- This is incurred for the following reasons (See Performance criteria on website).

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

2.10.3 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.

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 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 S.C. **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.

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 S.C., 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 – Mrs Heather Titcombe - 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(EQA) standards is suspected by the complainant, the Chief Executive of CPA(EQA) may be contacted;
- Where the UK NEQAS code of practice itself is the issue of 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 S.O. 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.

5.1.2 Assessors User Manual

User Manual for the assessors to print submissions and score the reports is available

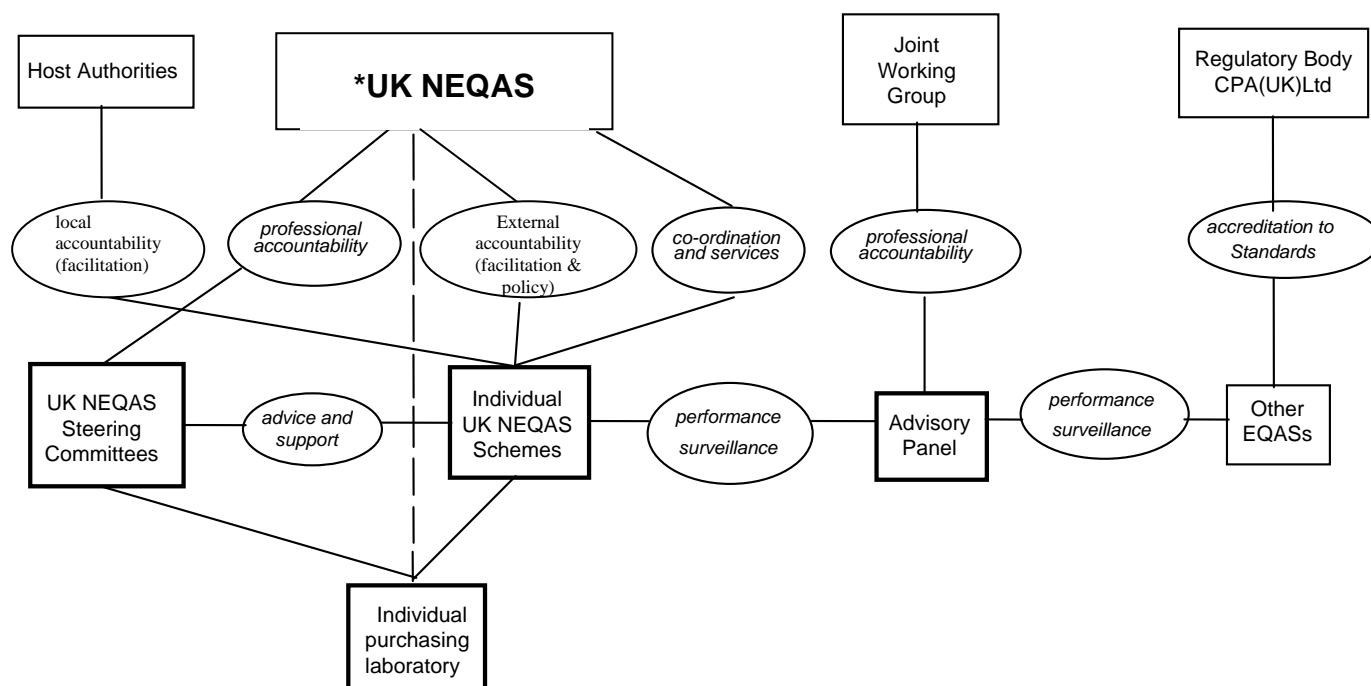
6.0 COPYRIGHT NOTICE.

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

UK NEQAS Code of Practice adopted at the UK NEQAS Consortium AGM & Conference, 9/10th October 2002

A. Definitions

A1. The Association is the United Kingdom National External Quality Assessment Service - a company limited by guarantee and a registered UK Charity.

A2. Members of the Association are defined as EQA Schemes or groups of EQA Schemes which have been accepted for membership of the Association.

A3. The UK NEQAS Consortium comprises representatives of member Schemes when they meet as a collective body.

A4. The UK NEQAS Executive Committee means those persons appointed to perform the duties of the Executive Committee as defined in the Memorandum and Articles of the Association. Those that are appointed Directors of the UK NEQAS company are responsible for complying with UK company law; those that are appointed Trustees of the UK NEQAS UK Registered Charity are responsible for complying with UK Charity law.

A5. The Executive Committee is accountable to the Consortium for implementation of the strategy for member Schemes, as agreed by the Consortium at its General Meetings.

A6. The term Organiser means the individual designated by the Executive Committee to be 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.

A7. Scheme Participants may be laboratories or individuals.

B. Membership Procedures

B1. Schemes shall be admitted to membership of the Association by the Executive Committee in accordance with the Memorandum and Articles of Association. Applications for membership shall be made to the Executive Committee on an application form available from the UK NEQAS Company Secretary and shall be accompanied by a signed statement from the Organiser that the Scheme or Schemes complies with this Code of Practice.

B2. 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 E3 where a subscription is charged.

B3. Only those Schemes admitted to full or associate membership of the Association by the Executive Committee shall be entitled to use the service mark "UK NEQAS" and associated logo. Use of the UK NEQAS service mark and logo by member Schemes and third parties is regulated

B4. 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 Association and required to rectify the non-compliance. Where a Scheme still fails to comply with this Code of Practice, the Executive Committee may prepare a written case for that Scheme to cease to be a member of the Association. In response, the member shall be offered three months in which to prepare a written case for remaining as a member of the Association. The documents shall be circulated to all

members, who will determine, by a majority vote of the Association in General Meeting, whether the member should be expelled from the Association, 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. Any decision to expel a member shall have immediate effect.

C. Member Scheme Management

C1. Participation in the Scheme shall be open to all UK laboratories offering a clinical service for analytes or investigations covered by the Scheme.

C2. The analytes or investigations covered by the Scheme shall be selected on the basis of their clinical relevance.

C3. 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.

C4. The staff involved in directing and operating the Scheme shall be appropriately qualified.

C5. The conditions of participation for UK laboratories providing a direct or indirect clinical service shall be those currently defined by the Joint Working Group for Quality Assurance.

C6. The Organiser of the Scheme 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. Agendas, Minutes and lists of attendees at Steering Committee/Specialist Advisory Group Meetings shall be copied to the UK NEQAS Office.

C7. The Organiser shall monitor those participants failing to maintain acceptable levels of performance and present reports to the appropriate division's National Quality Assurance Advisory Panel (NQAAP), which comprises nominees of the appropriate professional societies and is recognised by the Joint Working Group for Quality Assurance.

C8. The full, realistically calculated costs of operating the Scheme shall be fully recovered from participants' subscriptions. Schemes shall be non-profit making and any operating surplus shall be reinvested in the Schemes.

C9. Management arrangements shall enable continuity of the EQA service to participants.

D. Member Scheme Design

D1. 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 laboratory performance and professional advice and assistance where appropriate.

D2. Schemes shall enable the detection of inadequate performance by participants. The standard of participants with apparent performance difficulties should be improved by education rather than penalty.

D3. 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.

D4. Evidence shall be available to demonstrate the appropriateness, stability and uniformity (homogeneity) of the material distributed.

D5. The Scheme shall provide rapid turnaround of results and performance data to participants.

D6. A "correct" or target result should be identified and an appropriate (usually quantitative) evaluation of results be presented to allow comparison of individual participants' results with overall results.

D7. The Scheme shall conform to relevant safety standards and transport regulations.

D8. 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.

D9. The Scheme should share a common participant identification code with other UK NEQASs and co-operate fully with the development and maintenance of a unified participant identification code database. Information in the database shall not be used by member schemes to the detriment of other member schemes.

E. Obligations and Responsibilities of Member Schemes and their Organisers

E1. Organisers of member schemes shall keep the UK NEQAS Office informed of changes in schemes' details and activities. This shall include completion of an Annual Return and mid-year update as appropriate. Changes to scheme details and other information for publication (e.g. enhancement services and notice of participants meetings) shall be made promptly to the UK NEQAS Office and these amendments checked by Schemes after publication.

E2. 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. Full disclosure of all sources of UK NEQAS Scheme income shall be made. In addition, any additional income which supports the viability of the Scheme shall also be stated.

E3. The Scheme shall contribute to the operating costs of the Association's Office and the costs of the services provided by the Office, as determined by the Association and administered by the Executive Committee. This shall include costs of developing and maintaining the UK NEQAS website and unified laboratory code database.

E4. The Organiser of the Scheme shall uphold, support and promote the underlying principles of the Association as embodied in the Memorandum of Association, Code of Practice and policies agreed by the Consortium at Annual General Meetings and Conferences. Organisers shall play a full part in ensuring UK NEQAS is a harmonised, participant-responsive service and shall not damage the reputation of the UK NEQAS organisation as a whole through inappropriate action or inaction.

E5. Organisers shall achieve appropriate accreditation for their Schemes.

E6. All aspects of the work of a member Scheme shall be open to audit conducted by or on behalf of the Association. 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 and Code of Practice of the Association.

E7. 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.

E8. 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.

Appendix C

Assessors, Membership of Steering Committee and National Quality Advisory Assurance Panel For Genetics (as of 01/2010)

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
Mrs Kath Smith	Sheffield	2004
Mrs Carolyn Campbell	Oxford	2005
Mrs Carol English	Newcastle	2006
Mr Graham Fewes	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, Kate Martin (or oncology)	Amsterdam, Holland	2009
Ingrid Simonic	Nottingham	2010
Dr Kathy Mann	Cambridge	2010
Mr Richard Hall	Guys, London	2010
Heather Ward	Guys, London	2010
	Manchester	2010
Oncology Scheme	Location	Start of term of Office
Mr Paul Roberts (buddy for new assessor)	Leeds	2002
Mr Mike Griffiths	Birmingham	2003
Mrs Helen Dickinson	Leeds	2003
Mr Dom McMullen	Birmingham	2003
Mrs Sarah Ryley	Harrow, London	2004
Mrs Polly Talley	Sheffield	2004
Dr Fiona Ross	Salisbury	2005
Dr Sheila O'Connor	Leeds	2005
Mr Nick Bown	Newcastle	2005
Dr Manuel Teixeira	Porto, Portugal	2006
Mrs Sandra Birdsall	Cardiff	2006
Mr David Betts	Dublin, Eire	2008
Ms Markella Mikkelsen	Manchester	2009
Marianne Grantham	Barts, London	2010
Steve Chatters	GOS Haem, London	2010

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

Scheme Organiser is involved in all EQA rounds

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 S.O.		2002
Mrs Carolyn Campbell		PS & RCPATH	2005
Mrs Sarah Ryley	*Secretary		2005
Mrs Helen Dickinson	*Oncology specialist	UKCCG	2005
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 Roger Mountford	Observer	NQAAP	n/a
Mrs Sandra Birdsall			2009
Mrs Kate Martin			2010
Dr Ingrid Simonic			2010
* Steering Committee Executive			

National Quality Assurance Advisory Panel (NQAAP) for Genetics

Name	Role	Affiliation	Term of Office
Dr Roger Mountford	Chair	RCPATH	2003
Dr Roberta Goodall		ACB	2005
Dr Ann Curtis		CMGS	2006
Dr Su Stenhouse		CMGS	2006
Dr Nick Cross		BSH	2007
Ms Michele Fenlon		AGT	2007
Mrs Kim Smith		ACC	2010
Dr Tony Parkin		ACC	2010
Dr Sandi Deans	By invitation	Molecular Genetics Scheme Organiser	n/a
Dr Ros Hastings	By invitation	Clinical Cytogenetics Scheme Organiser	n/a

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:

Dr Roger Mountford
 Molecular Genetics Dept
 Liverpool Women's Hospital
 Crown St
 Liverpool
 L8 7SS

Appendix D

Clinical Cytogenetics covered by the Scheme

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

Constitutional

- Amniotic Fluid
- CVS
- Bloods
- Urgent Bloods
- Solid Tissues
- Fanconi Anaemia (Pilot)

Oncology

- AML
- ALL
- CML
- MDS
- Lymphoma and lymphoproliferative disease
- Solid Tumours

Technique Based EQA

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

The following types of EQA may be involved:-

1. **Slide Distribution** is a two part process. The first stage (Part A) involves the submission of slides and a written description of the karyotype from two cytogenetic cases. The second stage (Part B) of the assessment involves the analysis of two cytogenetic cases (from another lab) given the supplied referral information. Laboratories are asked to give the ISCN, a written description and provide an interpretation of the cytogenetic results (technical and analytical proficiency assessed).
2. **Retrospective reports** involve the submission of two cytogenetic reports and referral cards 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.
3. **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).
4. **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).
5. **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. **Slide Distribution** :- Slides plus written description where appropriate. Online documentation also to be completed.
2. **Retrospective reports**:- Copy of referral form, copy of cytogenetic report. Online documentation also to be completed.
3. **Case scenarios**:- No documentation - only online documentation to be completed.
4. **On-line EQA**:- No documentation - only online documentation to be completed.
5. **DNA**:- No documentation - only online documentation to be completed.

Example completed templates

The following completed templates are given:-

1. **Slide Distribution** :-
 - ***EQA Case Submission Form (p19)*** – 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 ‘Preliminary results information’ in section B.
 - ***EQA Case Assessment Form (p20)*** – section A will be filled automatically from section A of the EQA Case Submission Form uploaded previously by the submitting laboratory. Any previous investigations relevant to the interpretation of the case, e.g. parental bloods, need to be entered in section B.
2. **Retrospective reports**:-
 - ***EQA Case Submission Form (p21)*** – 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.
3. **Case scenarios**:-
 - ***EQA Case Scenario Assessment Form (p22)*** – select the case scenario (A/B) in section A.
4. **On-line EQA**:-
 - No template required.
5. **Validated samples**:-
 - No template will be required for the MRA or LPD schemes in 2010.

Laboratory No.	80000
EQA	Solid Tumour EQA 2007
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:	08/1234	Date of Birth:	01/01/1978	Sex:	Female
Sample Type:	Tumour	Date Received:	31/12/2008	Days to report:	14
Referral Reason:	Nasopharyngeal carcinoma				
Additional Information:	FISH probe details/manufacturer (All the information in Section A is given automatically to the reviewing laboratory. Under case number put the unique case ID e.g. 08T/108).				

B. Results	
Your Results:	47,XX,t(11;22)(q24;q12)[10] EWSR1 rearrangement detected [80/100].
Laboratory Comments: (include details of probe(s) or primers used)	Written description of karyotype. Details of any probes used e.g. probe name, manufacturer. Any additional studies undertaken to ascertain the karyotype. Any additional information you wish to relay to the assessors.
Preliminary results information:	Level of analysis if multiple probes used or more than one method (technique).

C. How you obtained the results		
	Preliminary result (if applicable)	Final result
Total No. of metaphases/interphases examined	100	10
No. of cells counted, scored or partially analysed		5
No. of metaphases fully analysed		5
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"/>
Are the slides of an adequate quality to detect the abnormality without prior knowledge of the abnormality?	Yes		Number of slides sent:	2					

Laboratory No.	80000
EQA	Solid Tumour EQA 2007
Year	2007 Autumn

PROSPECTIVE

EQA-Case Assessment Form

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

A. Referral Details			
Slide Case Number:	08/1234	Date of Birth:	
		Sex:	Unknown
Sample Type:		Referral Reason:	
Additional Information:	All of section A will be filled in automatically from section A of the submitting laboratory.		
Preliminary results Information:			

B. Results	
Your Results:	47,XX,t(11;22)(q24;q12) EWSR1 rearrangement detected.
Additional Comments:	Any additional studies that you would undertake to confirm this result (if applicable) PRIOR to reporting. To explain any local policies that determine the content of the report. Any additional information you wish to relay to the assessors

C. How you obtained the results	
Total No. of metaphases/interphases examined	6
No. of cells counted, scored or partially analysed	3
No. of metaphases fully analysed	3
Banding Quality Score	2

D. Your Report (up to 5000 characters)
Give a clear written description of cytogenetic result/karyotype. No interpretation of the karyotype is required.

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)	Probe details, manufacturer plus probe type.

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"/>

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 - if given Written description of cytogenetic result Interpretation of the results Any onward referral required Riders on reports/Probe details

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 Oncology Scheme

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 accreditation standards for External Quality Assessment Schemes (ILAC 43 standard), 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 'scheme'.

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

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 chairs of the National Quality Assurance Advisory Panels (NQAAPs), 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. The criteria for *poor performance* and *persistent poor performance* are proposed by the EQA scheme Steering Committee in consultation with the Scheme Organiser and approved by the relevant NQAAP.
6. The identity of a persistently poor performing laboratory will be made available to members of a NQAAP. Normally management of such laboratories will be undertaken by the NQAAPs. However, it may be escalated to the JWG if not resolved by the NQAAP.
7. Samples, reports and routine correspondence may be addressed to a named deputy, but correspondence from Organisers and NQAAPs concerning persistent poor performance will be sent directly to the Head of the laboratory or, in the case of the independent healthcare sector, the Hospital Executive Director.
8. 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.
9. When a laboratory shows poor 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* the Organiser will notify the Chairman of the appropriate NQAAP together with a resume of remedial action taken or proposed. The NQAAP Chairman should agree in writing any remedial action to be taken and the timescale and responsibility for carrying this out. Advice is offered to the Head of the laboratory in writing or, if appropriate, following a visit to the Laboratory from a NQAAP member or appropriate agreed expert.
10. A 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.

11. If persistent poor performance remains unresolved, 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.

12. 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.

July 2008 A J Howat
Chairman, Joint Working Group for Quality Assurance

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. All such investigations which the laboratory performs as a clinical service must be included. Any changes in the laboratory's requirements in this respect must be notified in writing to the Scheme Organiser.
2. 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.
3. EQAS samples must be treated in the same way as clinical samples.
4. The EQAS 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 appropriate Steering Committee, and in specified circumstances (section 7) the Chairman of the accrediting body, without the written permission of the Head of the laboratory. In the particular circumstances set out in Section 8, this information may be released as defined in the section. The identity of participants (name of laboratory and Head of Department) and the tests for which they are registered (but not details of performance) may be released on request to the Scheme Organiser, to the Health Authority, Hospital/Private Company in which the laboratory is situated.
5. 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.
6. 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.
7. All reports, and the data they contain, issued by EQAS Organiser are copyright and may not be published in any form without the permission of the appropriate Steering Committee.