Birmingham Quality Participants' Manual

Contents

1. General Information

1.1. Background

Birmingham Quality is the main UK NEQAS centre for the Clinical Chemistry division of Laboratory Medicine in the UK. The UK NEQAS service began at Birmingham in 1969; a brief description of its history may be found in Whitehead & Woodford (1981).[1] Birmingham Quality also provides some non-UK NEQAS services which are delivered to the same standard of operation as for its UK NEQAS services. Full details of all the EQA services offered can be found on the Birmingham Quality website at http://birminghamquality.org.uk.

1.2. Aims

- To provide professionally-led and scientifically-based EQA services with a primarily educational objective, to help laboratories appraise their performance and monitor improvements.
- To achieve this through operation, frequent distributions of multiple specimens and rapid performance feedback.
- To distribute EQA material which as closely as possible represents clinical specimens.
- To distribute educational or exploratory specimens to assess problem areas found in clinical practice.
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- To perform continuous assessment within rolling time windows of usually 6 to 12 distributions, providing information on total error, bias and consistency of bias ('A', 'B' & 'C' scores) through the use, wherever possible, of validated target values.
- To produce reports which are clear, informative, intelligible and structured to assist interpretation and enable use by different levels of laboratory staff.
- To give information on method performance as well as for the individual laboratory. This, is important for comparing and evaluating methods.
- To help to ensure clinical laboratory test results are accurate, reliable and comparable wherever they are produced.
- To improve patient care through the expert design and delivery of EQA programmes and the skilful interpretation and communication of the data they generate to all relevant stakeholders.

1.3. UK NEQAS Code of Practice

Please go to the UK NEQAS website for full details see the Code of Practice

1.4. Location

Birmingham Quality (UK NEQAS) is situated at the

Institute of Research and Development
Birmingham Research Park
Vincent Drive
Edgbaston
Birmingham B15 2SQ, United Kingdom

The PO Box address is: **Birmingham Quality (UK NEQAS), PO Box 3909, Birmingham, B15 2UE, UK,** but courier services should always be given the full address and post code above.

For a map, please enter B15 2SQ into a suitable online mapping service.

BQ is adjacent to the **Queen Elizabeth Hospital**, part of the **University Hospitals Birmingham NHS Foundation Trust (UHBFT),** and **Birmingham University**.

See http://www.birminghamquality.org.uk/contact-us

1.5. Administration

Birmingham Quality is administered as a separate self-financing unit within Division A of UHBFT, which provides employment and financial services. It is independent from the pathology services provided by UHBFT.

Some aspects of our services may be subcontracted; where this occurs, competent subcontractors are used, and Birmingham Quality remains responsible for their activities. Scheme design, performance evaluation and report authorisation are never subcontracted.

1.6. Staffing & Management

Birmingham Quality is directed by a Consultant Clinical Scientist with many years' experience of EQA work with designated UK NEQAS Scheme Organiser status. The Director is supported by the Deputy Director (a Consultant Clinical Scientist) and a second Consultant Clinical Scientist.

The above senior scientists all have UK NEQAS Scheme Organiser status and possess professional registration with the Health and Care Professions Council (HCPC). Designation as a UK NEQAS Organiser is by the Board of Trustees of the UK NEQAS Charity, based on experience and expertise.

A few EQA services involving very specialist assays are the responsibility of remote Organisers who are contracted by Birmingham Quality to carry out this activity.

The range of EQA services offered and the programme Director/ Organiser of the service can be viewed using the link: http://birminghamquality.org.uk/eqa-programmes

Day to day management of Birmingham Quality is the responsibility of the Director. Day to day management of the individual EQA services is the responsibility of the Scheme Organisers.

The Operations Manager, EQAS Programme Coordinator and their staff carry out sample preparation and distribution, data entry, report production and publication, communications and general clerical duties. All staff are employees of UHBFT and are solely employed in the provision of EQA services.

The Quality Team is responsible for the development, implementation and maintenance of the Quality Management System and maintaining compliance with ISO/IEC 17043:2010 — Conformity Assessment — General requirements for proficiency testing.

1.7. Local Links

Birmingham Quality has links with local Clinical Laboratory Services who provide preliminary assays on raw materials, and other services.

Birmingham Quality has a contract with NHS Blood and Transplant Service for the provision of blood products.

1.8. Communications

The telephone number is: 0121 414 7300 [non-UK +44 121 414 7300] which is continuously manned from 0830 to 1700h Monday to Friday, with voice mail recording at other times, on official holidays or in case of

high call volumes. Callers will be asked the nature of their request or enquiry, and will then be transferred to an appropriate member of the team (see below).

It is particularly important that participants co-operate with our Quality System requirements for telephone communications which is in place to better serve their needs. All callers will be asked for their name, laboratory identifier code (where relevant) and department and for an indication of the nature of the call, before it is passed to the most relevant member of staff for attention.

Most communications can be dealt with speedily and effectively by our highly experienced and knowledgeable administrative and scientific support staff without referral to senior staff. Callers can therefore be confident that they do not have to speak to the Organiser on each and every occasion. All contact information is logged and the outcome of calls and actions audited.

The FAX number is: **0121 414 1179** [non-UK +44 121 414 1179].

Birmingham Quality participants wishing to make general enquiries, should contact us via any of the routes described at http://www.birminghamquality.org.uk/contact-us

For non-participants, the departmental **email** address is **birminghamquality@uhb.nhs.uk**

Senior scientific staff have personal email addresses. These should only be used for messages of a specific nature which only the individual concerned can answer. They should NOT be used for EQA results, method changes or general enquiries as they are individual, private addresses, and as such may not be scanned each day or during holiday periods when the staff members are absent.

Director:	finlay.mackenzie@uhb.nhs.uk
Deputy Director:	rachel.marrington@uhb.nhs.uk
Consultant EQA Scientist:	jane.french@uhb.nhs.uk

1.9. Websites

Information about Birmingham Quality and the EQA services it provides can be found at the following address: www.birminghamquality.org.uk

The main UK NEQAS Website is at www.uknegas.org.uk . This provides general information about the UK NEQAS organisation as a whole, as well as specific information for each UK NEQAS centre.

1.10. External Regulation of Our Services

- **Accreditation**: Birmingham Quality is accredited by UKAS against the requirements of ISO/IEC 17043:2010 – Conformity Assessment – General requirements for proficiency testing. The scope of accreditation can also be viewed on the UKAS website:

  Scope of Accreditation

- **UK NEQAS Consortium** – Birmingham Quality has close ties with other UK NEQAS operations though the UK NEQAS Consortium. All UK NEQAS-designated services comply fully with the UK NEQAS Code of Practice

  Code of Practice

- **Steering Committees & Specialist Advisory Groups:** All EQA providers are required to seek advice from and report to Steering Committees and/or Specialist Advisory Groups. The Clinical Chemistry division of UK NEQAS is presently served by an overall Steering Committee (SC) which advises on overall policy matters, with Specialist Advisory Groups (SAGs) providing external scientific advice.

- **National Quality Assurance Advisory Panels**: All full UK NEQAS schemes (ie not surveys or non-UK NEQAS schemes) report to the National Quality Assurance Advisory Panel (NQAAP) for Chemical Pathology. The names of SC, SAG and Panel Chairs and Secretaries are available on the UKNEQAS website for any participants who wish to express comments or concerns about schemes and their operation.

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1.11. Other Links

Birmingham Quality has close links (formal & informal) with UK professional groups, EQA providers in other sectors, European groups such as CEN, EURACHEM and EQALM, and international organisations such as IFCC.

Birmingham Quality works with the WHO on the co-ordination of collaborative research, promotion of effective QA in health laboratories and assistance with the establishment of regional and national EQA schemes world-wide.

Links also exist with British Council, the International Atomic Energy Agency, and other organisations: British In Vitro Diagnostics Association (BIVDA), Medicines and Healthcare Products Regulatory Authority (MHRA), Association for Clinical Biochemistry and Laboratory Medicine (ACB), Institute for Biomedical Science (IBMS), European Federation for Laboratory Medicine (EFLM).

2. Terms and Conditions of Participation

2.1. Eligibility

Birmingham Quality services are designed principally for UK public and private sector clinical laboratories serving clinicians and patients. Non-UK clinical laboratories, those with purely research or industrial roles, manufacturers of diagnostic instruments and reagents, and other laboratories are also welcome to participate. Manufacturers may do so 'anonymously', whilst a product is not yet available on the market, or on an 'information only' basis, ie without receiving samples and returning results.

2.2. Terms and Conditions

The act of requesting registration or re-registering (whether by email, letter, web form, quotation or purchase order) confirms a participant's willingness to be bound by these terms and conditions.

For UK clinical service laboratories, the act of enrolling in a scheme confirms their willingness to be bound additionally by the current Joint Working Group (JWG) Conditions of Participation (the terms and conditions and other information about the Joint Working Group can be accessed via https://www.rcpath.org/profession/committees/jwgqa.html

Any manufacturer whose assay is represented in the EQA programmes also agrees to be bound by the JWG Conditions of Participation and may be brought to the attention of the Medicines and Healthcare products Regulatory Agency (MHRA) in the event of poor assay performance.

2.3. Period

Participation in all Birmingham Quality Schemes is deemed to be continuous with automatic annual renewal and invoicing for subscription fees for each NHS financial year (1st April to 31st March), unless Birmingham Quality are advised to the contrary, in writing, a minimum of one month in advance of annual renewal. Participation may begin at any time during the year; part-year charges are higher than pro rata.

2.4. Enrolment Procedure

Participation begins at the first distribution following receipt of fully completed enrolment questionnaires sent in response to a formal request to participate. Questionnaires gather full details of the participating laboratory and the methods it uses for the analyte(s) concerned.

As indicated above, enrolment may take place at any time. Visit http://www.birminghamquality.org.uk/contact-us for information about how to contact us with enrolment requests.

On enrolment, each participant is given a unique UK NEQAS laboratory code (now shared across all UK NEQAS centres), which remains associated with that participant indefinitely. Laboratories with more than one analytical area (eg routine & emergency laboratories) may make multiple enrolments, where Birmingham Quality will create 'daughter' codes (eg 10123A, 10123B). Laboratories at multiple sites but administered by a single department may receive separate codes. Reattribution of codes and data can be accomplished where laboratories close, merge or de-merge. Participant codes must not be disclosed to third parties.

2.5. Charges

Annual subscription charges are based on the full actual 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 as participation increases or if surpluses are generated. Equally they may be increased if costs rise or if participation decreases, though any such increase must be justified to the UK NEQAS Board of Directors before they can be implemented. Current charges are available on the Birmingham Quality Website http://birminghamquality.org.uk

2.6. Refunds

Refunds are not available; however, transfer of subscription charges to other EQA programmes may be possible under exceptional circumstances at the discretion of the Director.

2.7. Confidentiality

The fact of participation, raw data and performance scores are currently confidential between the individual laboratory, Birmingham Quality staff and scheme organisers, the NQAAP and JWG (for those laboratories in the UK which provide a clinical service and are consequently bound by the JWG Conditions of Participation) and are performing poorly. Performance scores (and some raw data) may be shared with the relevant NQAAP under defined circumstances as part of the routine reporting of persistent poor performance. These data may be shared with local management, regional QA officers, accrediting bodies, and suppliers of equipment and reagents where appropriate and necessary, but only with the participant's explicit permission.

Birmingham Quality reports are copyright and may not be copied, distributed, published or used for publicity and promotion in any form without the written consent of the relevant scheme Organiser on each and every occasion, though performance data may be shared with individual clients (eg GPs, clinicians, pharmaceutical companies) without consultation.

2.8. Use of Residual 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. They do not constitute in vitro medical diagnostic devices (IVDs) and EQA specimens are explicitly excluded from the scope of the IVD Directive and its successor Regulation.

No claim is made that they may be suitable for any other purpose or at any other point in time. Resale or distribution to third parties is strictly prohibited. It is accepted, however, that residual material may be retained by the participant and used as part of method evaluation. Only very limited supplies of fresh samples are available for this purpose.

If materials are to be used in research which is expected to be published, or if participation forms part of contractual agreements with third parties (eg in drug trials), written consent must be obtained from the relevant Scheme Organiser on each and every occasion.

2.9. Repeat Samples

Limited numbers of single samples or sets from a particular distribution are usually available to full participants who may wish to check aberrant results or evaluate new methods. Birmingham Quality reserves the right to ask why repeat samples are needed and limit their supply if this would compromise the service to other participants.

2.10. Reporting of Results

All full participants are expected to return results promptly within the specified reporting period. Those under the remit of the UK NQAAP are expected to return 100% of results within the relevant cumulative performance scoring period. Where a laboratory is unable to return a set of results, an explanation must be provided using the comments box on the online result entry page.

2.11. Demographic information

Participants are responsible for ensuring that the contact (including invoicing contacts), method and reporting units information held by Birmingham Quality is current and up-to-date. Method and unit information can be communicated using the online method update facility (available via the 'Edit' button on the online Results & Reports page). Participants will need their user name and password to use this facility.

3. Materials

3.1. Sources of Blood and Serum

The majority of serum used is obtained from NHS Blood & Transplant (NHSBT), whom Birmingham Quality have a contract with. Some schemes/analytes require serum from patients either collected specially by collaborating physicians or NHSBT (eg glycated haemoglobins), or pooled from residual patients' serum supplied by participants (eg high-level oestradiol).

3.2. Sources of Other Bodily Fluids

These are obtained either from healthy volunteers or from patients through special arrangements with collaborating physicians or participant laboratories.

3.3. Remnant Material

Use of laboratory remnant material for Quality Assurance purposes is covered by the Human Tissue Act 2004 and Birmingham Quality welcomes any donations from laboratories. Please contact Birmingham Quality if you have any remnant material that may be suitable for distribution through the schemes.

3.4. Informed Consent

Where additional material is obtained from healthy volunteers or patients, informed consent is sought prior to collection of the material.

Providers of materials to EQA schemes must ensure that donors are given sufficient information to enable them to give informed consent for this use. Birmingham Quality can supply generic patient information and a consent form for this purpose. General non-specific consent may not always be appropriate for some applications. Wherever possible and appropriate, samples should be anonymised so that they are not traceable back to the individual patient. Providers should ensure they have a paper trail and 'cradle to grave tracking' of these materials.

3.5. Safety

Blood collected by NHSBT is subject to the same UK safety testing procedures as blood used for transfusion. Other materials are either specially tested after obtaining informed consent from patients, or not tested and participants informed of this fact. The latter circumstances apply where the risk is minimal. Please read the safety notice below.

IMPORTANT SAFETY NOTICE

As for clinical specimens, Birmingham Quality samples should be handled as if capable of transmitting infection. Appropriate procedures should be used to minimise contact with samples and for their disposal

3.6. Initial Analysis & Storage

Primary materials are stored appropriately according to matrix (so as not to affect the critical analytes) after removal of samples for safety testing or analysis to establish analyte levels.

3.7. Pool Processing

The principal features of routine pool processing are available on request, but the emphasis is placed on minimum number of donations per pool and minimal disturbance to the matrix. Non-pooled material (i.e. a single donation of bodily fluid provided by an individual) will be used in preference to pooled material wherever possible and where volume constraints allow. From time to time, special pools are prepared to address specific problems or scientific/clinical issues (eg additions of known interferents). Participants are regularly informed in scheme reports of the nature and constitution of materials distributed.

3.8. Participant Handling and Storage of EQA Materials

It is recommended that EQA samples should be analysed immediately upon receipt. Where this is not possible, the samples should always be handled and stored by participant laboratories as closely as possible to the way they handle and store patients' samples. The length of time in storage should be kept to an absolute minimum and where the samples have been refrigerated or frozen, they should be brought to room temperature and mixed gently prior to analysis.

3.9. Transport

Where EQA samples require onward transportation i.e. from one participant to another, it is recommended that they are treated as patient samples and are transported according to local transport procedures. Birmingham Quality have tested the integrity of specimens during transportation and can assert that the quality of EQA specimens is not adversely affected for a maximum of 48 hours when transported via Royal Mail at UK ambient temperatures.

4. Online Services

Birmingham Quality recognises the importance of the Internet for communication with and provision of services to participants, as well as interaction with oversight committees, professional bodies and the diagnostic industry.

Birmingham Quality is committed to the development of unified, easy to use web interfaces which enhance the utility of existing services to participants and enable new services to be developed. Wherever possible, this will be done in collaboration with other UK NEQAS centres and schemes, so as to maintain a pan-UK NEQAS unified approach. The UK NEQASs for Microbiology (Colindale), Peptide Hormones (Edinburgh and Guildford), Cardiac Markers (Glasgow) and Andrology (Manchester) also use our online Results and Reports service.

Two services have been enabled: **Results and Reports** and **Interpretative Comments**. Please follow the sidebar links on our website for further information and to use these services.

If you have any comments on, or requests for Internet-based services, please contact us using any of the routes described at http://birminghamquality.org.uk/contact-us

5. Operations

5.1. Distribution Cycle

All schemes operate according to a regular cycle of activity, based nominally on 4, 6, 12 or 24 distributions per year. A distribution has a unique identifier (usually numeric) with fixed sample despatch and results return dates. When the distribution is generated, a 'snapshot' of participation (labs, analytes & methods) is taken for the duration of that distribution cycle. Changes in participation that occur during the current distribution cycle are incorporated before data processing.

5.2. Pool Distribution Policy

It is intended that within any given performance assessment period, a number of different materials will be distributed that assess the range of analyte concentrations agreed by our expert groups and advisors to be clinically important. How successfully this policy is delivered in practice also depends on scheme size and analytes, whether materials are multi- or single analyte and the availability of suitable clinical material.

5.3. Distribution Dates

The schedule for the current calendar year (and the next year when known) is available at http://birminghamquality.org.uk/schedules, but dates may be subject to minor changes dependent upon operational circumstances.

5.4. Method Classification

A crucial element of participation for all schemes is the correct assignment of method codes, since performance scoring may be method-based, and the provision of accurate method-related information is an important element of the service.

Methods are given unique codes in the computer system, with parallel coding or sub-codes for alternative reagents/calibrators etc. Considerable effort has to be expended by Birmingham Quality staff to ensure the accuracy of method coding and updating records when these change. Participants are required to co-operate with this process by completing fully and returning method questionnaires at the point of enrolment, and informing us of errors, omissions or changes at the earliest opportunity. Method and reporting unit information can be updated using the online method change facility.

It is essential that Birmingham Quality are informed of any departure from the manufacturer's stated protocol, together with supporting information on the validation of this approach (see JWG guidelines). Once a participant's enrolment in a scheme has been finalised, it is the participant's responsibility to notify us of any changes to their methods or reporting units. Our method update service is web-based and is accessed online via the 'Methods' button on the 'Results and Reports page'. You can select from a dropdown of methods or select the default option from the major manufacturer's products. If you are not using the system according to the manufacturer's instructions, please select the in-house category within your system's method principle. Method codes have been harmonised for UK NEQAS hormone schemes, Edinburgh (peptide hormones & tumour markers) and Guildford (peptide hormones) schemes.

5.5. Packaging & Mailing

Single samples or sets (depending on the scheme) for each distribution are mailed to the registered scheme contact(s) using the fastest and most appropriate route possible. First class mail is used for the UK, and airmail (with express surcharge where necessary). The packages are clearly marked 'open on receipt'. Packaging complies with current UK legislation for the mailing of pathological material.

Where there are separate samples for each analyte (eg steroids) tubes have colour-coded caps. All tubes are labelled with the scheme, distribution identifier, analyte (where appropriate) and sample number. The naming convention for the latter has been standardised across all schemes and comprises a sequential numeric distribution identifier plus a letter where there are multiple specimens in a distribution (eg 256A, 256B, 256C). Once the specimens have been despatched, the registered scheme contacts are sent an e-mail notification of sample despatch.

5.6. Results Documents

All schemes have distribution-specific request cards / results documents which are individual to each participant. These carry the laboratory code, a full list of the analytes available in the scheme (a box appears next to the analytes for which the laboratory is registered along with confirmation of their reporting units), as well as messages about sample handling and return of results. In some cases method confirmation is also included. They are under constant review to make them easy to understand and use, and may change from time to time to reflect improvements. The functionality of the Results document mirrors the Results return section of the online service.

5.7. Sample Handling

The general rule is that participants should treat EQA samples identically to those from patients. It is recognised that sample tubes and requests are different and multiple samples may be received for certain analytes. In principle; however, accession numbering and assay should be the same as for patients.

In order that there should be uniformity of handling amongst participants, it is recommended that if an assay is not to be performed on the day of receipt and specific storage conditions have not been specified on the results document, serum, urine or plasma-based EQA samples should be frozen at -20 °C or below, and thawed completely and carefully with thorough mixing on the day of assay. For other specimens (whole blood, human faeces, artificial faeces and artificial sweat) where specific storage conditions have not been specified on the results document, these should be stored at +4 °C until the day of assay.

The length of time for which the specimens are stored should be kept to an absolute minimum. Unless instructed otherwise, participants should ensure that ALL samples in a given distribution are analysed on the same day, with the same batch of reagents, and in the same analytical 'run', batch or calibration cycle, to ensure that unknown additional variability is not introduced.

Once analysis is complete, please retain any residual EQA material for troubleshooting purposes. Laboratories should store as they normally would do, but in the absence of a local protocol it is recommended that the storage conditions on the results document are followed.

5.8. Results Reporting Procedure

Unless specified otherwise, all results must be returned using our online service. This provides the most rapid means of reporting results, with real-time validation against plausibility limits and confirmation of submission.

Results should be entered in the units shown on the online service form, taking care to match sample numbers and avoid transcription or transposition errors. If the units displayed on your results document are different to your usual reporting units, please notify us using the online methods update facility.

Figures and decimal points should be unambiguous. Please do not enter leading zeroes. 'Less than' or 'greater than' results can be entered online using the '<' and '>' symbols as appropriate. Please do not leave a space between the '<' or '>' symbol and the numerical result.

In the unlikely event that the online results entry system is not available, results transcribed onto the original document may be FAXED or sent as an e-mail attachment to Birmingham Quality, **by prior arrangement with Birmingham Quality**. Results received by any route other than the online results entry service, not previously agreed with Birmingham Quality, will not be included in the data-processing for that distribution.

Please avoid obscuring results documents with sample or bar code labels and ensure that all figures and decimal points are clear and unambiguous.

Registered online service users may enter/update/amend their results for online service enabled schemes at any time while the distribution is open.

Late results may be entered online after the closing date and at any time up until the close of the next distribution. These will be incorporated into cumulative analysis at the next distribution. All late results are flagged as such in our database.

Null returns where there are no results available e.g. if there are no patients' samples to assay, if the assay is out of service, or if one or more results from a panel of analytes is missing, then enter XPL into the results entry boxes for the affected analytes/specimens and provide a brief explanation in the comments box at the bottom of the results entry screen. Where it is not possible to return any results for a particular distribution, please check the box at the top of the results entry screen marked 'Tick this box if you have no results at all for this distribution; you must provide a brief explanation in the comments box below'.

When entering results online, Participants should always **check the methods** for which they are registered, and make a correction if a change has occurred, using the online method update facility. Method changes can be applied retrospectively but only as far back as the distribution prior to the one currently open (2 distributions for the UK NEQAS for Clinical Chemistry).

5.9. Amendments Prior to Data Processing

Participants who discover an error in their reported results before the reporting deadline can amend their results via the online service at any time whilst the distribution is open.

5.10. Amendments After Data Processing

If errors are identified after the return-by date, requests to amend non-analytical errors should be made online under the usual Results button, ensuring the correct Distribution number has been selected. Requests for amendments can only be made for the distribution prior to the one currently open (2 distributions prior to the one currently open for the UK NEQAS for Clinical Chemistry). Simply edit the affected results and re-submit. The requestor should include their name and a valid reason.

Amending results is at the discretion of the scheme Organiser and is not an automatic entitlement. The Organiser reserves the right to request additional evidence in the form of the original output from the analyser.

All amended results are flagged as such in our database. Procedures for amendment and scoring of non-analytical errors ('blunders') are described in the 'Performance Problems' section of this manual. Problems associated with any errors made by Birmingham Quality will be amended as soon as practicable and a new report generated. There is internal audit of such occurrences, which are rare.

6. Data Processing

6.1. Data Handling

All Scheme data are held on secure network servers which are backed up daily. Data processing is performed using special EQA software modules which have been developed in association with the Wolfson Computer Laboratory since 1969. These allow all schemes to be optimally configured according to Birmingham Quality house style.

6.2. Calculation of Target Values

Target values are crucial to scheme design and usefulness and are the basis for accurate performance scores. In all cases, a robust estimator of the central tendency of the data set and its dispersion are calculated. Clearly the larger the number of data points the better the estimate, which becomes important when method-related target values are employed rather than those from all laboratories or groups of methods.

To eliminate the distorting effect of grossly atypical results, outliers are trimmed from both tails of the ranked data set, with a corrected estimate of dispersion (SD or CV) usually by the method of Healy (1979)[2] to allow for the removal of extreme values which are not 'true' outliers. The data processing for individual schemes is conducted using individually configured modules within the computer system.

6.3. Validity of Target Values

For target values to provide an accuracy base for method evaluation and comparison, they should be validated. For those analytes (eg drugs) which are exogenous to normal body fluids, weighed-in values which are independent from scheme data can be used to validate targets. For analytes which are endogenous and where reference methods exist (eg IDMS for steroid hormones), target values can be compared with reference values. Where there is no accuracy base, but internationally-recognised reference preparations exist (eg TSH), target values may be validated using recovery/linearity (dilution) exercises. These are performed at regular intervals throughout the year. Birmingham Quality is committed to continually assess the ongoing validity of its consensus and/or target values.

Where the ALTM is known to be ‘incorrect’ and the scheme contains sufficient users of mass spec field methods, the latter is used as the target value. This itself is validated by comparison with reference or candidate reference method values.

In the Glycated Haemoglobins scheme, secondary reference method values obtained from reference laboratory network members are reported to participants; however, these are not used as the target value.

6.4. Calculation of Performance Scores

As well as providing data on closeness to the target value in a given distribution, schemes employ scoring systems which yield a performance score averaged over a number of distributions and individual samples within a rolling time window to give a robust estimate of overall bias and its variability.

The scoring method used for all Birmingham Quality schemes is the ‘ABC of EQA’ system. Worked examples of how these are calculated and used are available under the ‘Centre’ button on the online Results and Reports page. You will need your user name and password to access this information.
Unlike many other schemes which conduct a series of discrete cycles after which an 'end-of-cycle report is prepared, UK NEQASs operate on the basis of continuous analysis for a rolling time window. Organisers have the option to exclude certain methods from the calculation of target values and/or certain pools from

scoring if these may perturb performance unduly or are atypical in any way. Such actions may be undertaken in consultation with the appropriate Specialist Advisory Group (SAG).

6.5. Acceptable Performance Criteria

Limits for acceptable performance scores are recommended by the Scheme Organiser and endorsed by the NQAAP after due deliberation and consultation with Organiser and SAG, to reflect the state of the art of analysis and encourage improvement. Procedures are used to identify those laboratories which have breached these limits on a set number of occasions within the cumulative reporting period. Schemes are required to provide information on persistent poor performers to the National Quality Assurance Advisory Panel (NQAAP) for Chemical Pathology. See Section 8.

6.6. Processing Surveillance

As each distribution is processed, Organisers carefully check the resulting data for integrity and consistency of results, and any unexpected shifts in method-related values which might signal a clinically-important shift in diagnostic products. If any are identified, the manufacturer is contacted so that the findings can be discussed and a preliminary brief report can be made. Target values for pools that have been distributed previously are given special attention. Sample reports are then prepared and parameters for graphic and tabular data checked and adjusted where necessary. Anomalies are corrected before reports are published.

7. Reports and Report Interpretation

7.1. Target Turn-Around Times for Reporting

All monthly, fully accredited Birmingham Quality EQA services have the following associated performance target: *"Reports are to be published to the web server before the next Distribution is open to UK participants."* For the fortnightly UK NEQAS for Clinical Chemistry, the target is 5 working days.

In reality, for the vast majority of Schemes, the time between distribution closure and publication of reports will be less than 5 working days. The exact time is recorded and is regularly audited.

The situation for Pilot schemes is inherently more variable owing to their fluid nature, but Birmingham Quality always aim to have reports published and available before the next Distribution is despatched. Once again, these dates are recorded and subject to audit and review.

7.2. Report Versions

The current definitive report is that on the secure Results and Reports website. When reports for a scheme distribution are published the name and date of authorisation are stated, and the time and date of publication are printed on each page. Unless specified in the report (eg an initial report awaiting republishing with a commentary) this may be considered as a 'final' report.

Revised reports including a participant's late or amended results are identified by the words "LATE Results" or "AMENDED" below the laboratory code at the top right of the report. Changes in target values resulting from inclusion of late or amended results are normally trivial (and will always improve target validity), and will be reflected in reports for subsequent distributions. On the rare occasions when revised reports are published for a distribution, the revised report is clearly identified as such, with reference to the date when the report which is replaced was published.

7.3. Distribution of Reports

The default status for report distribution is 'paper-free'. Participants may download their reports as electronic .pdf files from the secure Results and Reports website.

7.4. Report Formats

Schemes' reports are the main interface with participants, and a great deal of effort has gone into making these informative and easy to interpret.

All scheme reports are generated as A4 format PDF files, which display the data in a number of discrete tabular and graphic formats shared across related schemes.

Most scheme reports now have 'traffic light' colour coding, where symbols and their colour (green, yellow or red) indicate how close individual percentage biases are to the target value, and whether performance scores lie within or outside acceptable limits. Examples are available on request, but all reports share most of the following features:

- Distribution summary (tabular)
- Participation summary
- Method summary
- Minimum Analytical Performance Summary [MAPS] (where appropriate)
- Overall performance summary (graphical)(Performance Summary Icons / Cumulative Summary)

- Current performance scores and limits of acceptable performance
- Individual results obtained, target values, deviation from the target value (tabular)
- Histogram of all results (method group and individual results marked)
- Table of method-related results (means, SDs, CVs)
- Table of results, target values and deviations for all distributions in the cumulative assessment period
- Graphical indication of performance scores
- Graphical indication of method-related performance scores
- Table of method-related performance scores
- 'Snapshot page' (ABC of EQA) showing a selection of useful graphs and useful for troubleshooting performance problems
- Some schemes (eg neonatal screening) also have information on the interpretative elements of participation. Where appropriate, Birmingham Quality provide plots which combine information about the relationship between numerical results and their interpretation broken down by method
- Where relevant and appropriate for the scheme and its target value(s), Birmingham Quality may provide a standard uncertainty of the target value(s) calculated according to the principles outlined in ISO 13528 *"Statistical methods for use in proficiency testing by interlaboratory comparison"*

Guidance documents are available under the 'Centre' button on the online Results and Reports page. You will need your user name and password to access this information. These should be studied carefully, and our staff consulted if clarification is needed. All are under continuous review with the intention to extend harmonisation of both aspects of scheme design throughout our schemes and in collaboration with other UK NEQAS centres.

7.5. Result Validation

Birmingham Quality will send an email notification to the registered scheme contacts when pdf reports for a scheme have been published to the website. Each report is specific for the laboratory identifier and password entered.

The results for that distribution should be **checked to ensure that they are the ones returned by your laboratory**. Mistakes can occur if the submit button has not been clicked after results have been updated or if figures have been misinterpreted whilst being transcribed. Requests to amend non-analytical errors should be made on the web under the usual Results button ensuring the correct Distribution number has been selected. It is very important to check your report as soon as possible after publication as requests for amendments can only be made for the distribution prior to the one currently open. Simply edit the affected results and re-submit. The requestor should include their name and a valid reason. Amending results is at the discretion of the Programme Organiser and is not an automatic entitlement. The Organiser reserves the right to request additional evidence in the form of the original output from the analyser. All amended results are flagged as such in our database.

Also, it is crucially important that **participants' methods (and sub-methods, instruments, reagents, calibrants and reporting units where appropriate) are accurately identified**, especially where performance is assessed against the method mean. Any apparent discrepancies should be corrected using the online methods update facility. If the method or unit information you wish to specify is not available via the dropdown list on the method update facility please supply as much information as possible (manufacturer and model number of the analyser, manufacturer, description and product code of the reagent & calibrator, and reporting units in the 'Your comments' section.

7.6. Current distribution

Use the **distribution summary pages** to examine the deviation of your results from the designated target value and (if not the target) the mean (or median) of your method group for each analyte. If deviations are consistent with usual overall or method-related bias and cumulative (A, B and C) scores remain stable and within acceptable limits, then it may not be necessary to examine analyte-specific pages in detail. If, however, there are unusual deviations for certain analytes, types of material or analyte concentration which appear not to be shared by other users of the method, then detailed examination of the problem area will be required. (If these are very large, then non-analytical errors should be suspected.) Where appropriate, use the 'traffic light' colour coding to identify aberrant results.

In the case of schemes which use a single sample for more than one analyte and results appear to be divergent across many analytes all in one direction, the occurrence of a systematic technical error (eg faulty sampling or dilution, inappropriate delay in assaying) should be suspected.

In examining **analyte-specific pages**, participants should relate their results to the overall and method-related distribution of results for each sample as indicated by the histogram and table of method means and CVs. Apparently discrepant results which lie in the tails of the distribution might signify a non-analytical error, others which lie just within the distribution may simply reflect atypical, but not abnormal, variation. Where reports include a table of results for previous distributions (eg hormone schemes) it will be helpful to look at results for the same pool distributed on a previous occasion to check for pool and/or concentration-related effects.

7.7. Rolling Time Window Performance (A, B and C) Scores

One of the main purposes of a performance score derived from a number of distributions and many samples is to 'smooth out' the natural variation in deviations from target values over a number of distributions, by trimming extreme values and deriving a robust estimate of the central tendency for overall bias together with an index of its consistency. Thus when interpreting the performance score elements of reports, it is important to note that (a) a small number of atypical results is unlikely to affect overall scores, and (b) aberrant results which are numerous enough to affect performance scores will take some time to work their way out of the scoring 'window'.

The principal concern of EQA is the overall bias of participants' results and the consistency (variability) of this bias over time with different materials and different analyte concentrations. It is important to note that when the score that relates to ‘consistency of the bias’ ('C' score) is high, then the confidence which can be placed in the overall bias score (B score) is reduced (and vice versa). Also, the C score may relate to assay imprecision (and/or reproducibility), but only if there are insignificant pool- or analyte concentration-dependent variations in deviations from the target value or changes over time. Only internal quality control (IQC) can give a clear assessment of analytical imprecision.
When interpreting performance scores, participants should look for atypical results in a single isolated distribution (as above) and relate these to IQC data on the day of analysis, and then for shifts or trends over a number of distributions which might indicate a method- or instrument-related problem. Note that the C score always increases when the B score changes in either direction, so that this will occur when bias shifts and again if a correction is made. Only after a full period of stable performance (with or without a change in bias) will the C score decrease to low levels. The graphical elements of cumulative reports show this clearly in relation to acceptable limits of performance (not all schemes) and the overall behaviour of different method groups. Attempts should be made to correlate trends and/or shifts in bias with IQC data, which in

turn should indicate whether changes in personnel, data reduction, procedures, calibration, reagent batches or instruments are implicated.

The Performance Summary Icons (PSI) page provides the Participant with at-a-glance information about their performance. This page displays a 'penalty box plot' for each analyte in the scheme for which the participant is registered. A 'traffic light' banner representing the worst case performance achieved by the participant for either the B or C score associated with that analyte is incorporated into each penalty box plot. As each point on the graph represents a user of the same method as the participant, and the limits of acceptable performance are clearly marked, it is possible for the participant to ascertain very quickly if they are breaching the acceptable limits of performance and whether all users of the method agree. Clicking on the analyte-specific icon will take the user directly to the analyte-specific pages of that report to allow for detailed analysis of the distribution data.

7.8. Method Comparisons

Reports may include tables of performance scores for all methods with >3 users. Included will be an estimate of the central tendency of the method group (eg median) and its dispersion (eg interquartile range = 25^{th}–75^{th} percentile). It should be noted that method-related scores are less reliable when there are <10 users of the method. Nevertheless, it is often useful for participants to compare the performance of their method in relation to others, especially where target value validation experiments reveal possible problems with calibration, linearity or baseline security.

7.9. Method Reports

Facilities exist for reports to be based on a particular method rather than an individual laboratory. This has the same functionality in terms of data analysis and presentation, but individual results are replaced by the trimmed method mean. These reports are of value to participating manufacturers for monitoring their products, and to laboratories evaluating methods or undertaking a tendering exercise. Method reports may be requested on an ad hoc basis or received routinely by certain types of participant. Those interested should contact the relevant Scheme Organiser to discuss their requirements in detail.

7.10. Special Reports

The computer system allows Scheme Organisers to extract data in a non-routine way from the EQA database to investigate problems with methods or illustrate features of participation and performance. These are not normally distributed to participants, but requests can often be met if the content and purpose of the report are carefully specified. Transmission of such data in electronic form is preferred. Those interested in this enhancement to routine reporting should contact the relevant scheme Organiser. Also available are special reports for point of care testing co-ordinators and laboratory network co-ordinators. Please contact us for further information.

7.11. Use of Birmingham Quality Data in Publications

All elements of all reports are copyright (Birmingham Quality). Anyone wishing to include extracts of reports or any of their individual design elements must contact the Director of Birmingham Quality or the Scheme Organiser for permission to do so and must provide a copy of the manuscript before submission for their approval.

8. Performance Criteria - Limits of Acceptable Performance and Performance Problems

8.1. Performance Criteria

The current limit of acceptable performance for each scheme and analyte may be found at the top right-hand area of the 'Histogram' page of the scheme report.

8.2. Non-analytical errors

These are defined as 'blunders' made by participants, which appear as anomalous results (which may or may not be classified as outliers), and may fall into the following categories:

- Assaying the wrong samples
- Assaying the right samples in the wrong order
- Incorrectly transcribing laboratory results from computer systems or worksheets to results documents
- Use of incorrect units and/or conversion factors
- Technical errors, eg incomplete mixing after thawing, faulty sampling/pipetting, double addition etc.

It is important to note that atypical results that derive from assay failures which are recognised as such only after receipt of the Scheme report are not 'blunder's - they are **analytical errors** that have **not** been detected by internal quality control (IQC) procedures.

If blunders remain uncorrected, they contaminate the database and may affect target values (especially if these are based on method means) and individual performance scores. Requests for blunders to be corrected may be submitted as an amendment request using the online results return facility as described in the 'Operations' section of this manual. These are not routinely acknowledged, and are acted on at the next distribution, with publication of an amended report to our web service. A computer 'flag' is attached to each amended blunder and a cumulative record maintained for each participant.

8.3. Participation and Return Rate

According to NQAAP requirements for acceptable performance, participants are expected to return 100% of results within the relevant cumulative performance scoring period. Where a laboratory is unable to return a set of results, an explanation must be provided (see 'Null returns' in 'Operations' section of this manual).

Birmingham Quality will assess a laboratory's performance as satisfactory if they have in total up to 2 late and/or amended distributions from the last 12.

8.4. Performance Surveillance and Advisory Panel Liaison

The Scheme Organiser highlights out-of-consensus performance in the routine report by the use of scores, symbols, graphs, banners and 'traffic lights'. The fact of Birmingham Quality providing participants with a red banner or red traffic light constitutes a formal communication from Birmingham Quality of out of consensus performance, and separate communication about this performance problem may not be sent.

It is the responsibility of the Participant to act on, investigate and resolve all out-of-consensus performance. If there is a red banner for any analyte on the Performance Summary Icon (PSI) page, then this should be logged in their Quality Management System. For any red B or C score traffic light, participants are expected to both acknowledge and fix the problems as part of their routine Quality Management System.

Birmingham Quality is here to help. If participants are unsure as to why they have out-of-consensus problems or if they are having difficulties with their Root Cause Analysis, then they should contact us.

Birmingham Quality are required to report to NQAAP for Chemical Pathology laboratories performance who is persistently unacceptable. Initially Birmingham Quality will make contact with the participant inviting them to discuss action to correct the poor performance. If a satisfactory response is made and improvement in

performance ensues, no further action is taken. If poor performance persists or no response is made, then a Panel letter (direct from Panel Chairman to Head of Department with lab identity and UK NEQAS lab code disclosed) is written requesting that decisive action is taken to re-establish satisfactory performance; this may include a site visit by Panel members. If this fails, the Joint Working Group may take further action.

Where poor performance is purely method-related (eg all users have a large positive or negative bias), Organisers will normally work directly with manufacturers to assist with correction of any problem; analogous procedures are in place for apparently IVD-related problems (see JWG guidelines).

9. Exploratory Exercises

9.1. Recovery Experiments

These are undertaken either as a continuous part of the scheme design or as regular 'one-off' exercises (eg steroid hormones). Generally, a low endogenous analyte (or stripped) basal pool is prepared, which is then divided into the same number of portions as there are samples in a distribution. To these (except the basal portion), linearly related amounts of pure analyte in a suitable solvent are added and the resultant solution stirred to ensure complete mixing. Aliquots of these pools are then included in a single distribution.

Data processing is conducted in two different ways according to the scheme involved. Some (eg Thyroid hormones) analyse the individual recoveries for each addition, whilst others (eg Steroid hormones) use linear regression (analyte concentration observed vs amount of analyte added) to derive an overall indication of fractional recovery across the concentration range (= regression slope). The resultant data and Organiser's comments are made available to participants as a separate report (examples available on request).

9.2. Reference Method Exercises

Isotope-Dilution Gas Chromatography Mass Spectrometry (IDMS) is the reference method for a number of analytes in Clinical Chemistry (Stöckl et al 1996)[3]. It can be used to provide a highly accurate target value, independent of 'EQAS effects' caused by the proportions of different methods contributing to the ALTM or method mean. Such target values enable scheme data (especially method-related results) to be directly linked to an accuracy base of reference methods and materials, which enable routine methods to be probed for calibration errors and specificity problems.

In the past, exercises have been limited to cortisol, progesterone, oestradiol and testosterone in the steroid schemes, but have been extended to other analytes and schemes including total thyroxine in the thyroid scheme and creatinine in the eGFR scheme. Two approaches are taken, either to target a small range of pools, or to target all pools in a performance scoring period, and re-process the scheme scoring data using the GCMS target value instead of the ALTM. Copies of reports will be made available to participants shortly after the exercise has been completed.

9.3. Linearity Exercises

These are performed from time to time and usually involve mixing of high and low concentration pools in different proportions so as to obtain pools with linearly related concentrations in the same matrix. Sometimes materials may be physically manipulated to achieve concentrations outside normal ranges.

9.4. Interpretative Exercises

From time to time, Birmingham Quality will invite participants to complete questionnaires about their service, and include distributions of matched samples with a clinical question, which is used to assess how participants interpret results in clinical practice. An example of this is an exercise for alpha-1-antitrypsin (A_1AT). Participants were first surveyed to establish whether they offered the assay for adults and/or children, and to obtain details of reference ranges and analytical imprecision. A distribution was then made of a normal A_1AT sample and one designed to mimic a homozygous deficiency state. Participants were asked to give an interpretation of the results and recommendations for further investigations. The results were collated and a report published through the schemes.

The web-based **UK NEQAS for Interpretative Comments** is a primarily educational service which assesses the appropriateness of comments added to results by individuals.

10. Complaints and Appeals

10.1. Definition

A complaint is considered to be any communication, written or verbal, from internal or external sources indicating deficiencies relating to the identity, quality, durability, reliability, safety, effectiveness or performance of the EQA service. Formal complaints and other communications which point out deficiencies, difficulties or problems (which are classified by Birmingham Quality as errors) are recorded together with any response or action taken by us. These are audited by the Quality Manager.

10.2. Types of Complaint and How to make a Complaint

Most problems experienced by participants consist of minor misunderstandings or problems with specimens and reports, which can usually be resolved over the telephone by any member of staff. If difficulties persist, then participants with continued justified cause for complaint about any aspect of the service should communicate their concerns immediately to the relevant member of senior staff, preferably in writing (email, fax or letter) though a preliminary telephone call may assist in clarifying the issue and establishing the requisite action.

- Where the complaint is about **scheme logistics**, then the **Operations Manager** is the appropriate point of first contact.
- Where the matter is related to **performance assessment** and **scheme design**, the relevant **Scheme Organiser** is more appropriate.
- If the complaint concerns the **conduct of a member of UK NEQAS staff**, or a **satisfactory response has not been received** from the individual first contacted, then the **Director** should be contacted.
- If matters remain unresolved, or the action taken by us is not satisfactory to the complainant, the next step is to refer the complaint to the Chairman of the appropriate **Specialist Advisory Group** where it relates to scheme design, or the main **UK NEQAS Steering Committee for Clinical Chemistry** where it is a more general policy matter.
- If the issue concerns **performance assessment**, the **Chairman of the Advisory Panel** may also be contacted.
- Where lack of compliance with **ISO 17043 Standards** is suspected by the complainant, then in the first instance contact the Quality Team at Birmingham Quality using one of the contact options http://www.birminghamquality.org.uk/contact-us . If the complaint is not resolved to the satisfaction of the complainant then the **Executive Chair of UKAS** may be contacted.
- Similarly, where the **UK NEQAS Code of Practice** itself is the issue of concern, the **President of UK NEQAS** may be appropriate.
- In all cases, Birmingham Quality staff will provide the names and contact details of the appropriate individuals.

10.3. Appeals Against the Evaluation of Your Performance

If you wish to appeal against the evaluation of your performance, please contact us via any of the routes described at http://www.birminghamquality.org.uk/contact-us

Your appeal will be handled according to our complaints procedure.

With regards to complaints against the evaluation of your performance, the Directors decision is final.

11. Footnotes

11.1. Feedback

This Manual has been made as comprehensive as possible, but it is appreciated that revision may be required to reflect progress. Participants are invited to make comments and suggestions, not only on the Manual but any aspect of our schemes or procedures, so that amendments may be made for the next edition. Please contact Birmingham Quality with your comments & suggestions here: http://www.birminghamquality.org.uk/contact-us

11.2. Acknowledgements

The continued loyalty of all participants, which has enabled Birmingham Quality to develop and expand to meet the challenges of the new EQA environment, is acknowledged.

The careful work of Birmingham Quality staff, the support of colleagues at other UK NEQAS centres and advice from members of expert committees and professional bodies are acknowledged.

Birmingham Quality is grateful to our host the University Hospitals Birmingham NHS Foundation Trust and the support that they provide.

11.3. Further Copies of This Manual

This document is the current definitive version of the Participants Manual and may be downloaded or printed by Birmingham Quality Scheme participants for their personal use.

12. References

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2. Healy MJR (1979) Outliers in clinical chemistry quality control schemes. *Clin Chem 25: 675-679*
3. Stöckl et al (1996) Analytical specifications of reference methods - compilation and critical discussion.
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