QCMD

Quality Control for Molecular Diagnostics

Participant Manual

Version Number PM001/18

www.qcmd.org

Table of Contents

Introduction to QCMD and background to the QCMD EQA programmes

Quality Control for Molecular Diagnostics (QCMD) is an independent International External Quality Assessment (EQA) / Proficiency Testing (PT) organisation. QCMD provides a wide-ranging quality assessment service primarily focused on molecular infectious diseases with over 8000 participant registrations from over 100 countries. QCMD actively collaborates with many other National quality service providers worldwide.

About the QCMD EQA programmes

The aim of QCMD's External Quality Assessment programmes is to help monitor and improve quality within the clinical laboratory by assessing a laboratory's ability to use molecular diagnostic technologies within the routine clinical setting. The QCMD EQA programmes support the clinical laboratory's regulatory requirements and are also educational in application. The reports and practical feedback QCMD provides participants allows them to identify and resolve potential problems whilst monitoring the effectiveness of their laboratory quality assurance processes.

How the QCMD EQA programmes work

A registered laboratory is provided with an EQA panel (challenge) either once, twice, or four times per year depending on the type of EQA programme. The EQA panel consists of a series of samples (panel members) that are designed to resemble clinical specimens and/or assess specific analytical assay characteristics. The number and variety of test samples in an EQA panel is dependent on the EQA programme objectives with each challenge consisting of between 3 to 12 samples.
The laboratory is required to test these samples using its routine assay and standard procedures. The results from the laboratory testing and details of the laboratories set-up, assay method and procedures are submitted to QCMD on-line. Following closure of the EQA participant testing period, participating laboratories are provided with the EQA individual performance report. The individual report consists of the participant's individual results and performance within their immediate 'peer groups' as defined by method, and consensus from all participants within the EQA. In addition a supplementary report may be made available following the release of the individual report if deemed appropriate. The supplementary report includes any relevant additional information regarding the recent EQA challenge and distribution such as gene targets, extraction methodology used, etc and

any feedback from the QCMD Scientific Expert(s) for that EQA programme. Group specific regional reports are also provided to participating national quality organisations where appropriate.
The EQA process is outlined in figure 1.

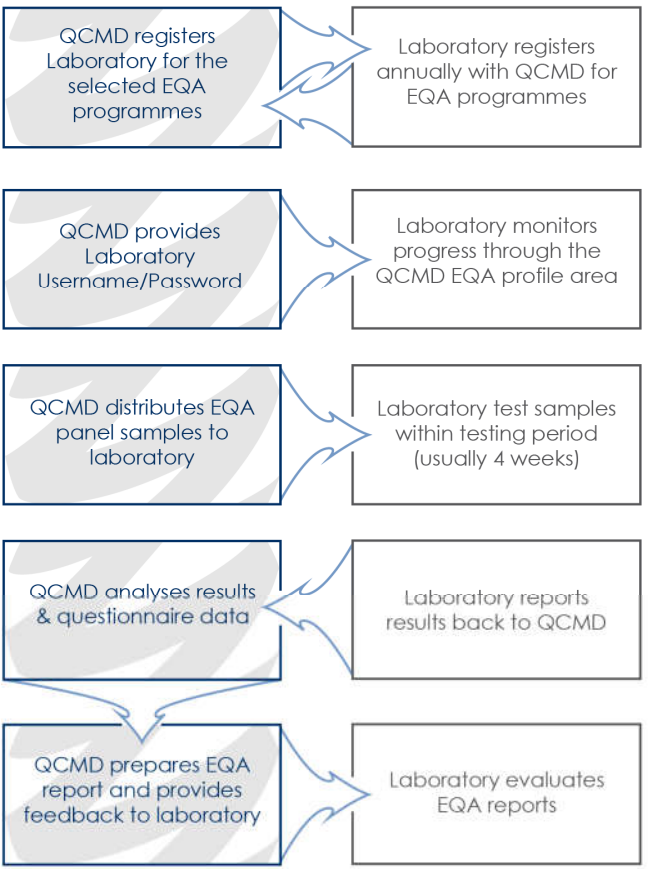

Figure 1The Outline of the EQA process

Why should laboratories participate in EQA?

EQA provides the laboratory with an independent performance appraisal. This supports the laboratory's quality assurance requirements and helps the laboratory demonstrate the ability to perform tests reliably and reproducibly. In addition, laboratories accredited to ISO15189 or an equivalent regulatory standard are encouraged to take part in EQA programmes, where available, or to participate in inter-laboratory comparisons (section 5.6 of the ISO15189 standard). EQA is also a mandatory requirement in many countries.

The aims and objectives of the QCMD EQA programmes

The general objectives of QCMD and the EQA programmes are:

- To provide EQA programmes and a quality assessment service fit for its intended use and in line with the Code of Practice and QCMD QMS.
- To provide EQA programmes that are continuously educational and provide appropriate and justifiable EQA challenges.
- To provide EQA programmes that supports the participating laboratory's regulatory requirements.
- Provide feedback and report information, upon request and where appropriate, for the monitoring of laboratory performance to authorised authorities, national quality organisations and participating laboratories.

The general objectives of the QCMD EQA programmes are reviewed and agreed upon by the QCMD Executive, International Advisory Board (IAB) and Scientific Experts. Each QCMD EQA programme also has its own specific individual objectives. These are defined within the programme project plan in conjunction with the scientific expert / group for the EQA programme.

The QCMD organisation

The QCMD Executive is responsible for the overall fiscal and legal management of the organisation. It is committed to the strategic vision of 'building quality & creating participant value' through the provision of 'state of the art' external quality assessment and innovative quality solutions to the International diagnostic community. The organisational structure of QCMD is outlined in figure 2.

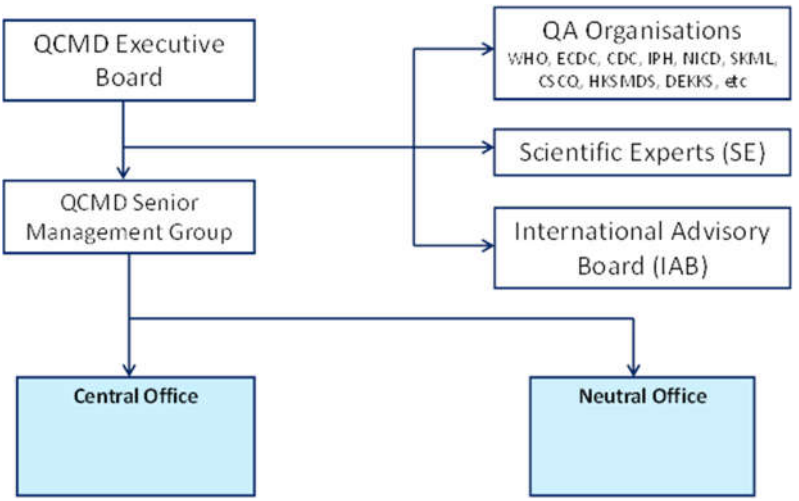

Figure 2: The Structure of the QCMD organisation

The QCMD Executive is supported by an International Advisory Board (IAB). The IAB consists of experts in specific fields such as infectious diseases and molecular diagnostics. They are integral in the scientific advancement and future development of the QCMD organisation.

The role and responsibilities of the IAB are:

- To review general objectives of QCMD and EQA programmes with the QCMD Executive.
- Recommend to the Executive potential scientific programme experts & expert groups.
- Propose 'new' potential EQA programmes for consideration.
- Advise and liaise with Industry (IVD manufacturers).

Within the International Advisory Board specific members have responsibilities for supporting statistical design.

The International Advisory Board and Executive are supported by independent 'advisors to QCMD' who attend Scientific Advisory meetings (SAM) and comment on QCMD topics including scientific, technology, regulatory, QC practices, statistics and informatics.

These organisations are represented through the International Advisory Board and key advisors to QCMD. Wherever possible, QCMD also collaborates with the national and International QA service providers and representatives from these organisations are invited to scientific advisory meetings.

The QCMD Central Office, located in Glasgow Scotland, consists of managerial, administrative, and technical staff with the skills and competencies required to administer the EQA service. The Central Office is responsible for all QCMD's daily business activities and it ensures that the quality management and EQA operations are conducted in agreement with the appropriate national and international regulatory requirements.

This includes the management of specialist subcontractor services such as couriers, and EQA material manufacturers where and when they are utilised.

All general customer enquires including programme registration, programme administration, and EQA panel distribution issues should be addressed to the central office by email at info@qcmd.org

The Neutral Office is responsible for the data collection, analysis, and generation of EQA reports in accordance with QCMD's EQA operating procedures and in compliance with the QCMD Code of Practice and QMS.

All laboratory information and EQA data is held confidentially and access to participating laboratories are provided through individual password protected profiles. The Neutral Office is the point of-contact for EQA performance and reporting related subjects. The primarily contact is by email at neutraloffice@qcmd.org. The Neutral Office can also be contacted by telephone on +44 141 945 6474.

EQA programme design

Each individual QCMD EQA programme has its own design specifications which are defined and agreed annually by QCMD in conjunction with assigned scientific experts / expert groups for each of the EQA programmes. The annual design specifications consider information and feedback from previous years and cover all aspects of the scheme. The specifications include; the panel composition and sample type; the technical requirements and online EQA questionnaire; the format of the EQA reports and statistical analysis used.

In addition the EQA specifications provide logistical and distribution information such as packaging and shipping requirements. The EQA annual design also considers feedback from previous QCMD EQA distributions.

Where appropriate, and in order to further support the quality of the EQA service QCMD subcontracts certain activities including EQA material preparation, testing, and shipping. QCMD does not subcontract EQA design and planning; EQA data analysis & evaluation or report generation and authorisation.

All QCMD EQA programmes follow a clear design pathway which is set out in the QCMD Code of Practice document and is in accordance with ISO17043:2010, CLSI MM14-A2 and other relevant national EQA guidelines. QCMD EQA programmes are covered by UKAS accreditation where appropriate.

The selection of EQA samples (panel members).

The EQA panel members are selected on the basis of their ability to meet the objectives and design specifications of the annual EQA programme. These objectives and specifications are both educational and regulatory in nature. They also cover both clinical and analytical aspects of the laboratory's testing procedure and methodologies. Hence the EQA panel samples aim to simulate the relevant properties of samples used within the routine clinical laboratory.

The number and variety of panel members in an EQA panel are specific to the design of each individual EQA programme. In General, QCMD EQA programmes consist of between 1 and 4 challenges per year with each challenge consisting of 3 to 12 panel members per challenge. Details are provided in the individual panel specifications which are also available on-line at www.qcmd.org.

The characterisation of EQA samples (panel members).

All EQA panel members, materials, and matrices are extensively characterised prior to use within an EQA programme. This also includes evaluation through pre-testing, preliminary EQA studies and technology specific independent testing. This testing ensures the integrity of the panel samples using a representative range of the current molecular technologies (commercial and in-house). Where appropriate certain EQA materials may be calibrated to available International Standards or suitable internal reference materials. Hence, the primary units of measurement used within the EQA programmes are those sanctioned by an International Standardisation body and/or those currently used and accepted within the routine clinical practice. For example, HIVRNA would be copies/ml and HCVRNA would be IU/ml. In EQA programmes where no International Standards are available and no unit is in common use, the unit of measurement are defined by the Scientific Expert group for that EQA programme.

Homogeneity & Stability

QCMD ensures that the EQA materials (primarily the matrix and target pathogen) are suitably Homogeneous in the elements (i.e. target pathogen) for which they are to be tested for within the context of the EQA and its outlined objectives. The EQA programme materials are also tested to warrant that they are suitably stable for the duration of the EQA scheme. Where appropriate, core materials are also assessed for stability across multiple EQA challenges.

The Homogeneity & Stability requirements for an individual EQA programme are defined within the EQA programmes specifications and supporting EQA programme plan in line with the requirements of ISO17043:2010. Any risks to the potential homogeneity and stability of the EQA materials will be identified during the planning phase and monitored throughout the duration of the EQA lifecycle.

The approach used for assessing Homogeneity is dependent on the individual EQA programme requirements but generally involves the following approaches or a combination of approaches:

- Batch to batch performance assessments
- 'Independent testing' of the final format EQA panels in selected laboratories using appropriately defined and validated molecular assays (pre and post EQA distribution)
- The assessment and evaluation of historic data and previous participant performance on same or similar EQA samples / materials used over multiple EQA distributions.

The Stability of the EQA panel materials is assessed by testing the EQA materials prior, during, and after the EQA distribution. The level of testing is dependent on the EQA programme and the maturity of the EQA programme. For most EQA programmes the EQA panel materials are stable if stored under the specified storage conditions for 2 years (NOTE: each EQA programme will have its own claims with regards to stability of the material used in it).

EQA pilot studies

New EQA programmes are introduced to the QCMD EQA portfolio as 'EQA pilot studies' on an annual basis. EQA pilot studies are conducted under the same criteria as full QCMD EQA programmes but they are not accredited by UKAS. If the interest in an EQA pilot study meets expectations and there is scientific justification, successful pilot studies are elevated to the full QCMD EQA programme status and are recommended for UKAS accreditation in subsequent distributions, where appropriate.

Participation in the QCMD EQA programmes

QCMD EQA programmes are offered internationally. Any laboratories conducting molecular based tests for the diagnosis of infectious diseases who wish to take part in a formal EQA / PT programme are eligible for inclusion. Accordingly, if a laboratory requests to participate in an EQA programme QCMD will endeavour to provide the service to any laboratory from any country.

EQA Participation is either directly through QCMD or through one of the QCMD coordinating organisations or collaborating national EQA providers.

Please contact the QCMD central office for more details via info@qcmd.org.

Fees for EQA participation

The QCMD EQA programme year runs from the 1st January until the 31st December and a list of QCMD EQA programmes is published annually in advance of the upcoming EQA programme year. Participants can choose to register for multiple EQA programmes on an annual basis and receive a reduction in the fees. Alternatively participants can register for individual EQA programmes throughout the year. EQA Programme registration is on a first come, first serve basis and QCMD reserves the right to carry an order forward to the next distribution if a specific programme is fully subscribed.
For some EQA programmes there may be an additional shipping charge, please check the details of the shipping requirements which are provided in the individual EQA specifications.

Please note, refunds shall be at the discretion of the QCMD Executive Office and are not normally made if a participant withdraws from participation after the invoice has been issued or materials have been sent.

What is included within the EQA

The EQA participation fee includes the EQA panel, on-line access to EQA data and reports through a unique password protected profile area. Past EQA data and trend analysis, multiple dataset processing, individual performance report, full participation certificate and where appropriate a supplementary report. .
Regional reports are also provided through QCMD collaborators where agreed

Confidentiality

All communication with participants in the EQA programmes is treated in a professional and confidential manner. Participants are provided with a unique code number for identification purposes and all results reported through a secure confidential participant profile area.

Please note: It is also the responsibility of all collaborators, national QC providers and distributors to maintain participant confidentiality.

Distribution and shipping

The number of EQA panel distributions per year is dependent on the individual EQA programme. For the majority of QCMD EQA programmes there shall be one, two, or four challenges per year.

Please note, in some geographical regions where QCMD works closely with a National QC provider or collaborator the frequency of EQA distribution is defined in line with the local requirements.
Participants are notified of the scheduled EQA distribution by email approximately 1 week prior to shipment.

The transportation of the EQA panels to participating laboratories is coordinated by specialist courier services in accordance with international guidelines (e.g. IATA) and to the specifications provided by QCMD.
Where QCMD has international or national representatives, distributors or EQA providers coordinating the local distribution of the panels to the individual participants it is the local providers responsibility to ensure that the EQA panel is distributed to the participant. Under these arrangements the participant should contact the local provider if there are any problems. On receipt of the EQA panel, participants are required to confirm receipt and condition of the EQA material on-line via their QCMD web-site profiles. The QCMD Central Office should be informed immediately if the panel does not arrive in the expected condition via info@qcmd.org or by telephone on +44 141 945 6474.

Testing the QCMD EQA panels

The participating laboratory has approximately 4 weeks to test the panel, answer the technical questionnaire, and report their results back to the Neutral Office via the QCMD online IT system. The EQA panel should be tested according to the instructions provided and following the laboratory's routine clinical protocols for molecular testing as closely as is possible. Participants who have not reported their results approximately 2 weeks prior to close of reporting are formally reminded by email through the Neutral Office.

Reporting EQA results to QCMD

Each participating laboratory receives a unique username and password. This allows access to the on-line QCMD IT EQA Management system (QCMD-ITEMs). Participants can use the participant profile area to monitor their progress, manage their EQA tasks, and report their results and any additional technical information.

For laboratories that have difficulty accessing the QCMD-ITEMs on-line or do not have access to the internet, QCMD alternative results reporting forms can be obtained by contacting the QCMD Neutral Office. These should be completed manually by the authorised laboratory representative and returned to the Neutral Office by either fax or email (if available).
Participants have a defined period within which to test and report their EQA results back to QCMD. Laboratories who fail to report their results within the allotted timeframe may not be included in the full data analysis and final EQA programme report.
After the close of testing and report phase of the EQA, the individual report (which includes the panel composition) is made available 'on-line' to paid participants through the laboratory's individual participant's profile area.

Please note, from time to time it may be necessary for a Neutral Office representative to contact a participating laboratory for additional information in order to support a laboratory's external quality assessment process. In these circumstances the laboratory will primarily be contacted by email.

EQA data analysis

All EQA programme results and participant data are collated through the QCMD IT EQA Management System (ITEMs) under the direction of the Neutral Office. The data analysis techniques used are based on approved procedures developed in accordance with the requirements of ISO17043 and as described in the QCMD Code of Practice. Standard procedures are followed in order to safeguard the integrity of the data analysis process. This also ensures that the processes are consistent across EQA programmes and that all laboratories are assessed fairly. Further details are provided in the QCMD reports and through the Neutral Office.

The use of statistics in QCMD EQA programme analysis

The statistical methods used at QCMD are designed to meet the goals of each EQA programme. They provide participants in the EQA programmes with meaningful information and support the EQA assessment process. The statistical design requirements for each EQA programme are defined in conjunction with the advisor to QCMD on Bioinformatics and Statistics giving consideration to the requirements of ISO17043 and other documents. Changes to the statistical evaluation processes or recommendations for the inclusion of new processes are made through the International Advisory Board and validated off line prior to their full implementation into the EQA process.

The statistical methods used within the QCMD EQA programmes are documented, managed, and maintained through the quality management system. Procedures for establishing key statistical practices for standard deviation, identifying and deal with outliers, and other statistical tools are defined within the Neutral Office statistical methods documents.
Any statistical queries can be addressed to the Neutral Office by email via neutraloffice@qcmd.org.

QCMD EQA Reports

QCMD aims to provide reports that are intuitive and easy to understand. After close of the EQA results return phase, EQA participants receive an individual report generated by the Neutral Office. Individual reports provide laboratories with an overview of their performance within an EQA challenge in relation to their method type, and where appropriate the consensus from the overall participants within the EQA programme. Depending on the objectives of the EQA programme most QCMD individual reports fall within the following categories:

- Qualitative
- Qualitative & Quantitative
- Molecular Typing / Genotyping
- Drug resistance and/or sequence based QA.
- Multiple pathogen
- Custom (only available to specific collaborator groups).

Further details regarding the individual report types can be found at www.QCMD.org. On QCMD approval the individual reports are released to participants in the EQA programme on-line through their participant profile areas.

On completion of the EQA programme, the QCMD Executive in consultation with the Scientific Expert for specific EQA programme may commission the QCMD Neutral Office to review and analysis any additional data / information reported within the EQA programme and issue this within a supplementary report. National EQA providers or country specific EQA groups are also provided with an additional country specific EQA report.

EQA Performance scoring

The QCMD EQA panels contain a range of samples, designed to look at different aspects of assay performance. Panel members are designated core proficiency samples on the basis of scientific information, clinical relevance and experience (published literature and professional clinical guidelines) and, where available and appropriate, previous EQA history. Laboratories are expected to correctly analyse and report the panel members designated as core proficiency samples within the EQA distribution in order to show acceptable proficiency.

EQA panels may contain samples designated as educational samples that are not expected to be reported correctly from a regulatory perspective. Educational samples may be included to look into analytical aspects such as limits of detection or detection of less widely known strains of a pathogen. For some programmes educational samples are often recent circulating strains. In addition, samples that are initially introduced as educational samples often become core samples in future EQA programmes as assays develop and the strains themselves become of increasing clinical importance.

In addition, Laboratories who report indeterminate results on both positive and negative samples shall have their results scored as incorrect. Where possible the laboratory's performance on 'like samples' is monitored through different rounds of the EQA programme. The performance scoring mechanism is regularly reviewed and before applying the scoring mechanism it is validated annually through the QCMD Advisor on Bioinformatics and Statistics.

QCMD monitors laboratory's performance over time based on the reported quantitative variation between duplicate panel members within the EQA challenge and, where appropriate, across EQA challenges.
The mean variation and standard deviation are calculated from the quantitative variation reported between duplicate panel members by each participant using the same unit of measurement.
The individual report provides a plot of previous and current observations.

For the majority of the qualitative EQA programmes sample status is based on the peer group consensus of all results returned from all EQA participants. The rationale for each sample status is:

Frequently detected: More than 95% of datasets recorded the correct positive result.

Detected: Between 65% and 95% of datasets recorded the correct positive

result.

Infrequently detected: Less than 65% of datasets recorded the correct positive result.

Negative: A panel sample that does not contain the target and produces an unequivocal negative result.

Therefore, sample status is only used for the scoring of the EQA data and it is not a measure of the 'strength' of a positive sample nor is it dependant on technology.

The scores awarded for qualitative EQA data were based on the sample status. The scoring system is represented in the following table, where 0 is 'highly satisfactory' and 3 is 'highly unsatisfactory'. Colour has been included as an extra visual aid.

Scoring system based on the assigned sample status

Sample status	Participant's result		
	Negative	Not determined	Positive
Frequently detected	3	3	0
Detected	2	2	0
Infrequently detected	1	1	0
Negative	0	3	3

In order to compare participants' quantitative results, quantitative analysis for each panel member is provided in relation to EQA assessment groups.

EQA assessment groups are established using the molecular workflow information reported by all participants within this EQA challenge / distribution. The principal level of assessment is at the individual method level which is defined based on the "amplification/detection method" reported by laboratories using the same or similar amplification/detection methods.

To allow meaningful assessment at the individual method level the EQA assessment group must consist of 5 or more datasets. If there are not sufficient datasets at the individual method level then participant's results will be included within a higher EQA assessment group based on whether it is a commercial or in house technology/method. The highest level assessment grouping is all reported results using the same unit of measurement (i.e. Copies/ml or IU/ml).

The individual report provides a breakdown of participant reported values on each of the panel members within an EQA challenge / distribution. Participant results for each panel member are presented to allow comparison to the "mean" within your EQA assessment group and the overall consensus for each sample within this EQA challenge / distribution.

Feedback to EQA programme participants

The aim of all EQA programmes is to provide clear and unequivocal assessment of participants on general laboratory performance using molecular technologies. This is achieved through the EQA reports and technical feedback at different stages of the EQA programme cycle. The general performance of participating laboratories is measured against peer results generated through consensus from the EQA programme. In addition, where there are sufficient numbers of datasets, the technology methods used are grouped and assessed to allow comparative analysis.
The EQA programmes are both regulatory and educational in their approach. In order to assist laboratories in the evaluation of their performance a score is provided within most EQA programmes (with the exception of some pilot studies). The intention is that participating laboratories use this score and the data within the EQA reports provided to monitor their performance over time and to take action on improving performance when identified.
QCMD also monitors the performance of laboratories on the designated 'core' panel members within an EQA distribution. This is either directly or through feedback to a regional National regulatory authority. See section below.

In general, EQA participants are expected to correctly report the designated core samples within an EQA distribution. A participant that fails to correctly identify a core panel member within a distribution is considered to be below the minimum performance criteria and this is identified within the individual report and highlighted to the participant. Laboratories that consecutively fail to detect core panel members within the same EQA programme or across EQA programmes may be contacted by QCMD in order to establish if they have a particular problem and if QCMD can provide help in anyway.

Feedback to National regulatory authorities

Where the responsibility for laboratory performance management resides with

a National regulatory authority QCMD may be required by law to provide details of laboratory performance within that region / country. Where required QCMD may report poor EQA performance, failure to participate or submit results to the national regulatory authority in line with their specified requirements.

Participant EQA problems & appeals

Where data from an EQA programme indicates a potential sample problem the situation is investigated through the quality management system (QMS). This is usually through the formal complaints process as outlined in the QCMD Quality Management System. The investigation is generally supported through the QCMD Neutral Office, but may require input from the Scientific Experts allocated to the project.

Any participant experiencing a potential problem within the EQA should communicate this directly to the Neutral Office as soon as possible. The Neutral Office will deal with these issues on an individual case by case basis through the comments and complaints handling process. The Neutral Office may contact the participant in order to request further information regarding the problem. Where necessary assistance in reviewing the problem may also be obtained from the Scientific Experts and or a representative of the independent International Advisory Board.

Participants who wish to question or query a specific EQA programme or appeal against an evaluation, may submit a written request through the QCMD Neutral Office or use the comments section provided on-line. Appeals will be reviewed in accordance with QCMD's comments and complaints procedure. All appeals will be reviewed on a case by case basis. If an appeal cannot be resolved immediately through the QCMD Neutral Office, it will be referred to the independent International Advisory Board who will make a final decision regarding the query.

Collusion and falsification of results

The potential for the collusion and / or falsification of EQA results is considered during the design and planning for the individual EQA programmes. In the interests of the individual participants and the professional integrity of the EQA programmes, every effort is made to ensure that the risk of collusion and falsification of results is kept to a minimum.
Any laboratory or laboratory representative found to be in collusion with

others shall be immediately removed from the study and may be reported to their national QC provider or authority, if appropriate. Any laboratory or laboratory representative found falsifying results shall be immediately removed from the study and may be reported to their national QC provider or authority.

Please note: EQA participating Laboratories should not communicate with any other participating individual or laboratory concerning EQA programme results until after the closing date of the relevant programme. A laboratory should not send any panel samples or a portion of the samples to another laboratory for analysis unless it is part of their routine practice or they have been given specific permission and instruction to do so from QCMD.

A laboratory may not receive any panel samples or a portion of the panel sample from another laboratory taking part in the EQA programme for analysis unless it is part of their routine practice or specific permission has been granted from QCMD.

Copyright & Publication of EQA programme data.

All material used within the QCMD EQA programme reports, supporting documents, and on the QCMD website is protected by copyright, whether explicitly marked copyright or not.

Participants may download material from the QCMD Web site only for personal and non-commercial use. However the subsequent copying, redistribution, or publishing of any EQA report and or associated materials, data or images is strictly prohibited without the prior written permission of QCMD.

QCMD encourages and supports the dissemination of the EQA programme information for scientific purposes and if participants wish to report data or information from the QCMD EQA reports, QCMD asks that they obtain approval from QCMD prior to publishing or presenting the data.

References, supporting standards and guidelines

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CLSI/NCCLS MM14A Proficiency Testing for Molecular Methods**;** Approved Guideline.

QCMD-CoP001 QCMD Code of Practice.

ILAC-G13:08/ 2007 Guidelines for the requirements for the competence of providers of proficiency testing schemes.

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