Weqas

GLOBAL PROVIDER OF QUALITY
IN DIAGNOSTIC MEDICINE

PARTICIPANTS MANUAL

www.weqas.com

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Contents

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1. Introduction

1.1 The history of Weqas

Weqas is a self-funded "not for profit" organisation hosted by Cardiff and Vale University Health Board, Cardiff. Initiated in 1968 to assess the analytical performance of Clinical Biochemistry services in the Cardiff area, the Programme quickly expanded to include all hospitals in Wales and by 1971 funding was provided by Welsh Government.

With the cessation of Welsh Government centrally funded development in 1993, the Programme became self-financing and was offered as a National EQA Programme to all laboratories in the UK and Ireland. Over the course of the next few years the Programme expanded its repertoire, participant numbers and quality of services and in 1997 Weqas became the first EQA Provider to attain accreditation by Clinical Pathology Accreditation and similarly in 2012 became the first Clinical EQA provider in the UK to attain ISO 17043:2010 Conformity assessment - General requirements for proficiency testing. It is now the largest EQA provider in the UK, with over 900 participants.

1.2 Our Personnel

Weqas employs a team of scientists with a wealth of experience in delivering services in Laboratory EQA, Point of Care (POCT) EQA, Reference method development and Internal Quality Control (IQC) production.

The Weqas Director is a Consultant Clinical Biochemist with over 40 years' experience in Laboratory Medicine, 20 years of which has been in the quality of diagnostics as Director of Weqas. She is also the National POCT Clinical lead for Wales representing POCT in Welsh Government Advisory Committees and chairs the National POCT Strategy and POCT Delivery groups. She has held posts as Executive Board member of the European Committee for External Quality Assurance Programmes in Laboratory Medicine (EQALM), chair of the ACB National Audit Committee in the UK and chair of the International Federation of Clinical Chemistry (IFCC) Committee on Analytical Quality. Further information about our personnel is available on our website https://www.weqas.com/contact/personnel/

1.3 Weqas EQA Programmes

Supplying to more than 35,000 sites per month, Weqas provides over 50 EQA Programmes, including external audit, performance analysis and an educational advisory service. As well as Healthcare pathology laboratories, these services are also provided to independent pharmacies, primary care physicians, occupational health providers, forensic pathology services, veterinary pathology laboratories, clinical trial units and diagnostic companies. The organisation, (Cardiff and Vale University Health Board, operating as Weqas) is accredited to ISO 17043:2010 - Conformity assessment - General requirements for proficiency testing (certificate no.4301). The most recent issue of the schedule of accreditation is available from https://www.ukas.com/wp-content/uploads/schedule_uploads/00013/4301Proficiency-Testing-Single.pdf

Weqas' Programmes are underpinned by commutable metrological traceable samples, informative reports and a team of experienced scientists and Point of Care co-ordinators.

At Weqas, clinical material (patient or volunteer samples) is collected, prepared / manipulated, analysed, and distributed to laboratories and POCT sites for analysis and/or clinical interpretation. The results / clinical interpretations are assessed against criteria determined by the Director and approved by the Steering Committee. Education and support are central to the organisation's objectives.

The aim of EQA as defined by the International Federation of Clinical Chemistry is to:

- To provide a measure of "state of the art" for test precision and accuracy.
- To measure performance against defined standards.
- To supplement IQC procedures within a laboratory.
- To assess analytical methods.
- To identify errors, both imprecision and inaccuracy.
- To act as an educational stimulus.

Weqas fulfils these aims and offers its participants powerful statistical tools to prevent, identify and eliminate errors.

For a full list of all our Programmes, Services and analytes please download PL-QLB-WEQBrochure from www.weqas.com

1.4 Weqas Reference Laboratory

The Weqas Reference Laboratory is a Joint Committee on Traceability in Laboratory Medicine (JCTLM) listed Reference Measurement Service Provider, part of a European Network of highly specialist laboratories providing accurate target value assignment of clinical material to assist in the global harmonisation of Pathology results. This is the only laboratory currently in the UK providing this service. The reference Laboratory is accredited to the International Standard ISO 15195 Laboratory Medicine - Requirements for Reference Measurement Laboratories and ISO 17025- General requirements for the competence of testing and calibration laboratories.

The Reference Laboratory uses primary and/or secondary reference methods in order to give stated, traceable analyte values in calibrator, QC and EQA material. Where possible Certified Reference Materials (CRMs) are used to corroborate target values. Reference Laboratory services are outlined on the website Reference Measurement Services - Weqas

2. Weqas enrolment process (the contract)

As an existing or prospective participant in our EQA programme(s) you will find a wealth of information on our website. **https://www.weqas.com/**

Full details of the enrolment process is provided at https://www.weqas.com/participantzone/ , along with frequently asked questions, subscription charges for both UK and non-UK participants, distribution dates and a link to the Weqas website portals.

Our participant zone is designed for both newly enrolled and existing participants. If you are not yet enrolled with us, and you wish to enrol on our programmes, please contact us for more information by emailing **contact@weqas.com** or by completing the **contact form** on the website.

The Enrolment Process includes: Completing the enrolment document, providing a purchase order, completing a method questionnaire and finally registering for the Weqas Web portals for online reporting.

2.1 Terms and conditions of participation

- Weqas is hosted by Cardiff and Vale University Health Board, Cardiff, UK (the legal entity).
- Invoices are raised by "Cardiff and Vale University Health Board". Failure to pay the invoice **within 14 days** will result in cessation of the programme and procedures initiated to recover the debt.
- Annual Subscription covers a period from **April 1st to March 31st** and is administered on an advance-payment basis. Order numbers should be included on the returned enrolment forms. For an electronic copy of the enrolment form please contact Weqas.finance@wales.nhs.uk.
- For existing customers**, participation will be deemed to be continuous, unless advised in writing** of any discontinuation.
- Participants that notify us of cancellation before 31st March will not be charged any cancellation fees for the following financial year.
- Participants that notify us of cancellation between 1st April and 30th June 2024 will be charged only for the service they have received prior to cancellation.
- Participants that notify us of cancellation after 30th June 2024 will be charged for the full enrolment year. No refunds will be given.
- In the event of a participant failing to pay the annual subscription fee by the due date, the Programme Organiser reserves the right to terminate the annual subscription without notice and the participant will be liable for the payment for services provided.

- The liability of Weqas and Cardiff and Vale UHB to the participant in any annual period resulting from or in connection with the provision of the programmes to the participant, shall under no circumstances exceed the amount of the Annual fee paid by the participant.
- Participants can join at any time throughout the year and will be invoiced on a pro rata basis.
- All reports, and any data contained therein, issued by the EQA Programmes are Copyright and may not be distributed, published or used for promotion in any form without the permission of the Weqas Director.
- These conditions shall be governed by and construed in accordance with the law of England and Wales
- If there are any additional unforeseen charges following regulatory requirements or charges following Government edits, we reserve the right to pass on such charges at cost to participants.
- All healthcare providers are eligible to participate in the Programmes.
- User accounts will remain active for 8 weeks following the cancellation date. After that period, requests for historic reports will need to be submitted to Weqas and charges will apply for this service.

2.2 Copyright

All reports are the property of Weqas and should be used by participants for the purpose of performance evaluation, quality improvement and education. Reports will not be printed or reproduced without the consent of the Programme organiser. Data or reports from the Programmes should not be used by IVD manufacturers for marketing purposes.

2.3 Confidentiality

Programme anonymity is preserved on reports and documentation made available in the public domain (or to other participants) by allocating each laboratory with alpha character or numerical codes. The codes are unique to the laboratory and used in all correspondence. There are secure and controlled storage areas for all confidential data. All confidential papers that are not stored are shredded prior to disposal.

The EQA code number and name of the laboratory and the assessment of individual performance are confidential to the participant and will not be released by Programme Organisers without the written permission of the Head of the laboratory to any third party *other than* the Chairman and members of the appropriate National Quality Assessment Advisory Panel (NQAAP) *and* the Chairman and members of the Quality Assurance in Pathology Committee (QAPC).

Further information on poor performance surveillance and the role of the NQAAP and QAPC is described in section 7.

The identity of a participant (name of laboratory and Head of Department) the analytes (or investigations) and EQA programmes for which that laboratory is registered (but *not* details of performance) may also be released on request to the Health Authority, Hospital Trust/Private Company in which the laboratory is situated after a written request has been received.

2.4 Code of Conduct

Weqas staff will treat all information supplied by a participant in strict confidence. High standards of corporate and personal conduct, politeness, selflessness, integrity, objectivity, accountability, openness, honesty, equality and leadership is promoted within the organisation. Feedback on staff performance and participants experience is greatly appreciated; both positive and negative. In the event of a complaint, please follow the complaints procedure detailed in Section 5.3.

3. Weqas Web Portals

Weqas offers a full online interactive service for our programmes for submission of results, accessing reports and access to data for performance troubleshooting. Weqas is currently in the transition phase of migrating all our EQA Programmes over to one new IT platform; Weqas Connect. This portal will replace both Weqas Interactive and POCT Interactive (CueSee) allowing all programmes to be accessed through one portal. Participants will be informed directly as each programme is migrated. Most of our POCT programmes are available through our Weqas interactive or Weqas Connect portals, however two programmes, POCT Glucose & Ketones and POCT Urinalysis are managed through a third-party website.

The new look and much improved IT portal **Weqas Connect,** has been designed by our in-house team of developers taking on board feedback and suggestions from participants. The portal combines the positive features of the two current platforms, providing greater flexibility of device and location registration and an extensive repertoire of reports available at all access levels, in a more stable and intuitive platform. The biggest change relates to the introduction of a hierarchy of registration i.e., Participant, Group and SuperGroup. This means that with one log-in you can access reports for individual locations within an organisation, view reports for multiple participants across a network or for multiple groups across a region. It is important that you let us know how you want us to set up your hierarchy. Please note that you will no longer retain your old participant code on Weqas Connect. The format of the new participant codes will be WQ12345, WQ12346 etc… Details of How to use Weqas Connect is available as video tutorials on our new learning zone, https://www.weqas.com/learning-zone/

3.1 Weqas Interactive and Weqas Connect portal access.

Access to the Weqas portals for reports and result entry is strictly controlled. For security reasons, access levels must be authorised by your Head of Department. Web registration forms are available to complete online from: https://www.weqas.com/website-registration.

Full lab access users will have access to all reports relating to your laboratory. For Weqas Interactive, additional contacts can be added on completion of the website amendment forms. https://www.weqas.com/participant-login/amend-user/ You can also amend your existing user details/registration by completing the 'Update User Contact Details' form via the following link: https://www.weqas.com/participant-login/update-user-contact-details/ to notify Weqas of changes in user status, so that we can ensure that access to your laboratory's performance data is only available to the appropriate personnel. Please be aware, once a username has been issued, it remains active until Weqas is notified that it is no longer required. **It is therefore the responsibility of each participating laboratory to notify Weqas when a registered web user leaves a laboratory or changes their email.** We can also provide access on a regional or network basis; however, signed permission from each laboratory Head of Department will be required, please contact us on: https://www.weqas.com/contact/ to set up this service.

However, depending on your permissions, Weqas Connect has a self-service functionality whereby participants with Administrative login has full user management within their organization hierarchy i.e. create additional users, additional contacts, deactivate users, edit user accounts, set notification preferences, create distribution letters, manage instruments and Programme registrations. This can be provided on a participant, group or supergroup level facilitating network and regional oversight. Full details on the participant administration functions and how to manage users are available on https://www.weqas.com/learning-zone/

3.2 POCT interactive website (CueSee)

This portal will be closed from October 2024 and all programmes migrated to the Weqas Connect portal, please ensure that you have downloaded all your reports by this date. If you still require reports after this date, these can be made available until September 2025, however, you will need to contact Weqas for access. For this portal, access for Group Administrator level is restricted to POCT Co-ordinators that have successfully completed the website training course and assessment. A series of web guides are available as part of the training package and are also available to download from our resource page on our website. https://www.weqas.com/resourcelibrary/. Please select **Category:** Web Instructions/Forms.

Part 1 - how to set up the database.

Part 2 – how to enter results.

Part 3 – how to generate reports.

Part 4 – how to use web tools and the query function.

As part of the website competency assessment, A Group Administrator is asked to Set-up 2 Users in the Demo database including site location and contact details, assign the correct Method / Meter / serial numbers to the Users, produce Distribution letters for the Users, and enter the results for the Users.

Once this has been completed successfully, the Group Administrator log- in is activated on the live site.

Group Administrators will have access to all reports relating to their organisation. More than one Group Administrator access can be provided if you wish. POCT users will only have access to their named location, as registered in the Weqas POCT database. POCT users requiring access to more than 1 location will receive a

separate username for each location. Please be aware, once a username has been issued, it remains active until Weqas is notified that it is no longer required. **It is therefore the responsibility of each participant to notify Weqas when a registered web user leaves the organisation or changes their email.** Please notify Weqas of changes in user status, so that we can ensure that access to your organisation's performance data is only available to the appropriate personnel.

3.3 Result Entry

3.3.1 Weqas Portals – Weqas Interactive and Weqas Connect

For Programmes on Weqas Interactive, a copy of the result entry form and the distribution close date is dispatched with the samples. This is for information only and to assist you in documenting your results. Instructions for entering results via the web are available on https://www.weqas.com/download/weqas-interactive-guide-lab-level-user/ for a laboratory or POCT Co-ordinator and on https://www.weqas.com/download/weqas-interactive-guide-section-level-user/ for a section user.

For Weqas Connect, customizable letters/ result return forms to be used within your organization can be downloaded from the Distributions tab. Details on how to download these and how to enter your results are available on https://www.weqas.com/learning-zone/

All results for our EQA Programmes must be returned via the respective web portals (deadline by midnight on the "return by" date).

3.3.2 POCT interactive website (CueSee)

A copy of the Instruction Sheet is dispatched with the samples. Instructions to Group Administrators (POCT Co-ordinators) on how to create a customised distribution letter for their own POCT users and how to enter results are available in the respective Programme Guides.

Results can be returned to Weqas by post, e-mail, self-web entry or telephone (as detailed in the Service Level Agreement.). The default option is web entry. Instructions for entering results via the web are available from Weqas on the resource page at https://www.weqas.com/resourcelibrary Please enter **POCT web** in the search box and select the relevant instructions for your Programme.

The deadline for phone, mail, e-mail or faxed results must reach Weqas by 5.00 pm on the **"end period"** date. Individual POCT Users (Sites) can also return their results via the self-web entry. Please contact Weqas POCT Team for website instructions regarding entering your results.

3.3.3 Units

SI Units should be used whenever possible. Please ensure that the results are entered for the correct units on the web page.

3.4 Database Changes

3.4.1 Method Changes

The reports incorporate longitudinal analysis of data over time, therefore information relating to method details and analyte requirements are strictly time dependent. For this reason, we need adequate notice of any changes to the database regarding the range of analytes, method / analyser details. In order to guarantee that the changes are processed for the correct distribution, please ensure that the new details are completed at least 7 ***working days prior to the distribution date of a programme***. Method details can also be changed by the participant up to the date that the Distribution is created (7 working days before dispatch of samples). Unfortunately, it will **not** be possible to process method changes or analyte additions once a Distribution has been created. For more information on Weqas method change instructions, please download the **WEQAS Participant Interactive Guide – Lab level user** as detailed above.

3.4.2 Programme Enrolment Changes

Changes to programme enrolment must be authorised by Weqas before they will take effect. Requests for programme additions / deletions should be sent in writing either by post or email at least 3 weeks before the sample dispatch date. If in doubt, please contact the Weqas Laboratory EQA team or POCT EQA team on the telephone numbers in section 5.1.

3.4.3 Change in contact details

Please inform Weqas immediately of any changes to contact details relating to samples, reports, invoices or

web users.

4. Programme Design

The matrix, frequency, number of samples, and analyte list for each Programme are detailed in the Weqas Brochure which can be found https://www.weqas.com/services/ simply click the "download our brochure" link. Individual documents detailing the purpose and scope of all our programmes are available on our website https://www.weqas.com/services/eqa/

Instructions for use and stability of the samples are available in the Intended Use documents. https://www.weqas.com/participantzone/intended-use-sheets/

Statistical methods, the evaluation criteria and example reports are available in the Interpretation of EQA Reports for Laboratory EQA https://www.weqas.com/download/how-to-interpret-your-report/and Interpretation of EQA Reports POCT EQA Programmes https://www.weqas.com/download/how-to-interpret-your-poct-report/

4.1 Sample Dispatch

In the **UK**, samples are sent out by first class post from Royal Mail and are usually delivered within 48 hours. A schedule detailing the dates of sample dispatch and the distribution closing result return dates is available on our website: https://www.weqas.com/participantzone/distribution-dates/

In the event that samples have not arrived within this time period, please let us know and we will send you a repeat set. In the event that there is a delay or change to the published dates, participants will be informed of the delay / change by email and the dates updated on the website. Please check the website for any amended dates.

For **overseas participants**, we offer 5 delivery options:
Options 1 is standard Airmail service from Royal Mail (3 to 5-day ambient delivery).
Option 2 is a priority handling and tracking service from Royal Mail (up to 3 days ambient delivery, but not guaranteed). **This is the default service in use and should be suitable for delivery of most of our samples.**
Option 3 is an ambient guaranteed next day delivery service by Courier;
Option 4 a dry ice guaranteed next day delivery service by Courier; and
Option 5 a dry ice guaranteed next day delivery service by Courier where samples are shipped in bulk 2 or 3 times a year rather than per Distribution. Please allow 4 weeks lead time to start this service from date of request.

4.2 Late Results

All EQA programmes have a 2 or 3 week return window and you will not be able to enter your results after the "return by" date. However, in exceptional circumstances Weqas may be able to accept late results. Please contact Weqas for advice.

4.3 Reports availability

Reports are normally available on the web portals within 7 working days after the "return by" date. The assigned value is not released until after this date. A longer turnaround time will be required for reports for programmes with interpretive exercises or special studies e.g., Porphyrin case studies, Interference studies or specificity and sensitivity studies. However, these will usually be available within 15 working days. In the event that there is a significant delay in providing the reports, participants will be notified by email and via the website.

Users of the Weqas interactive and Weqas Connect portals have the option to request their reports in PDF format, emailed directly to their in box. Please ensure that your preferences are checked in the respective portals. For more information on Weqas report generation options, please download the **WEQAS Participant Interactive Guide – Lab level user** as detailed in section 3.1 and the corresponding video tutorial on Weqas connect.

4.4 Subcontracting Services

Various aspects of the EQA Programme can from time to time be subcontracted (e.g., homogeneity and stability testing, target value assignment). Weqas does not subcontract the planning of the EQA Programme, the evaluation of performance or the authorisation of the final report. If any subcontracting is necessary, Weqas will be responsible for ensuring the quality of this work.

4.4.1 EQA Material

Weqas uses clinical samples (patient or normal donors) wherever possible to ensure commutability of results with patients' samples. Most of the clinical material is collected, prepared, and manipulated in house, including homogeneity and stability testing. However, some specialist (or unstable) material is sourced from a third party i.e., blood gas, co-oximetry, POCT Hb, fFN and INR. All suppliers are evaluated for their competency to provide these services. All samples should be treated as if they were patient samples.

5. Communication and participant feedback

5.1 Helpline – +44 (0) 2920 314750 *e-mail* contact@weqas.com

Participants at any time during the working day can ring up for advice on their quality assessment. The Programme staff who have experience in, and information relating to, many different methods are there to discuss problems and aid in the interpretation of QA data. Quality assessment material can also be provided with known target values to aid them in evaluating new methods or to check existing ones. The troubleshooting and educational activity is an important part of the service. A log is kept of each call and all calls are answered as soon as possible. A telephone answering service is in operation at all other times.

5.2 Retention of Documentation

Written communication (paper) received from participants are retained for 3 years. Electronic copies of communication (email or web forms) are retained for 10 years.

5.3 Complaints procedure

Participants can contact us through our website, e-mail or by telephone. All complaints are logged and acknowledged within 2 working day. If a non-compliance cannot be rectified within this period, the participant is informed. The investigation will be undertaken by a Senior BMS or higher grade of staff. The outcome of the investigation will be reported to the complainant in a timely manner.

The communication log/non-compliance reports are audited monthly for trends, corrective action and quality improvements. The results of these audits are documented and brought to the attention of the relevant section head. Audit summaries are presented at the Steering Committee meetings.

5.3.1 Transcription errors

Details of what to do in the event of a transcription of results is covered in section 7.2.

5.4 Appeals Procedure

Participants wishing to appeal against the outcome of their performance evaluation must write to the Director, clearly outlining the issue and enclosing any relevant documentary evidence. E-mail communication is considered acceptable. An acknowledgement that an appeal has been lodged will be issued within 2 working days. The responsibility for investigating the appeal and determining the outcome will reside with the Director. The investigation will be carried out in a timely manner, in most cases this will be within 10 working days, however, depending on the nature of the appeal, the investigation may have to be referred to the Steering Committee. The Director will write to the participant with the outcome (e-mail may be used) detailing the reasons for the decision. In the Directors absence this is devolved to the Deputy Director. In the event that the appeal is upheld an amended report will be issued.

5.5 Participants Views and Feedback

Participants can at any time comment on the Programme either directly to the organisers or through members of the Steering Committee. These comments are encouraged and provide important information on areas for improvement of the service. Feedback is also encouraged at the annual user group meeting each year (see next section) through both the formal feedback session or informally with the Programme organiser and staff in attendance. A customer satisfaction questionnaire is also distributed periodically.

5.5.1 User Group meetings and Training Days

A two-day National meeting in the form of scientific seminars and EQA workshops are organised annually with additional ad hoc Regional training days for EQA interpretation and POCT Web Portal training. An invitation to the annual meeting is sent to each participating laboratory. Participants can also subscribe to the meeting on their enrolment form. In the past these meetings have proved invaluable to both the Programme organisers and participants in demonstrating the benefits of the Programme, discuss current hot topics and in gathering information on participants' perceptions of the Programme. Programme participants are given the opportunity to exchange views, to question the organisers and to discuss problems and strategies. To download presentations from our Training Day, please go to the Education and training page in our Participants zone, https://www.weqas.com/participantzone/education-training/

For information on forthcoming Training Days please see the Events area on the Home Page: https://www.weqas.com/event/. Please contact Weqas to arrange additional training in your Region.

6. Weqas Steering Committee

The professional advisory structure is a Steering Committee, which meets with the organisers of Weqas three times a year. The Steering Committee has nominated representatives from Chemical Pathologists, Clinical Biochemists and Biomedical Scientists with relevant expertise to provide the breadth and depth of advice to cover all the parameters in the Weqas Programmes.

6.1 Membership of Steering Committee

The full list is available on our website: https://www.weqas.com/aboutus/steering-committee

6.2 Terms of Reference of Steering Committee

The Steering Committee advises the organisers on the overall operation of the Programme, including the frequency of distribution of materials, the types of materials to be distributed, the clinical appropriate ranges, the clinically relevant performance criteria, methods of statistical analysis and data presentation, and the desirability of introducing new investigations to the Programme. All members of the Steering Committee are available to receive comments from participants, although the majority of comments are received by the organisers via the "helpline".

The Steering Committee is not concerned with the performance of individual participating laboratories except where this might indicate a failure in the operation of the Programme. The Steering Committee discusses with the organisers criteria for satisfactory performance and they have agreed that the responsibility for the acceptance of such criteria will rest with the NQAAP. There are also additional experts which act as Clinical Advisers in specific Programmes.

7. Performance Surveillance

Surveillance of performance for Pathology Laboratories within the UK is co-ordinated by the QAPC.

The QAPC exists to co-ordinate and protect high professional standards of quality assurance practice of all pathology disciplines. It fulfils its remit by supporting the work of the NQAAPs that have responsibility for monitoring External Quality Assurance programmes in each of the disciplines of pathology and through them the performance of the UK laboratories participating in those programmes. Full details of the remit of the QAPC and NQAAP are available from the Royal College of Pathologist website: https://www.rcpath.org/profession/committees/qapc.html

7.1 Reports to NQAAP

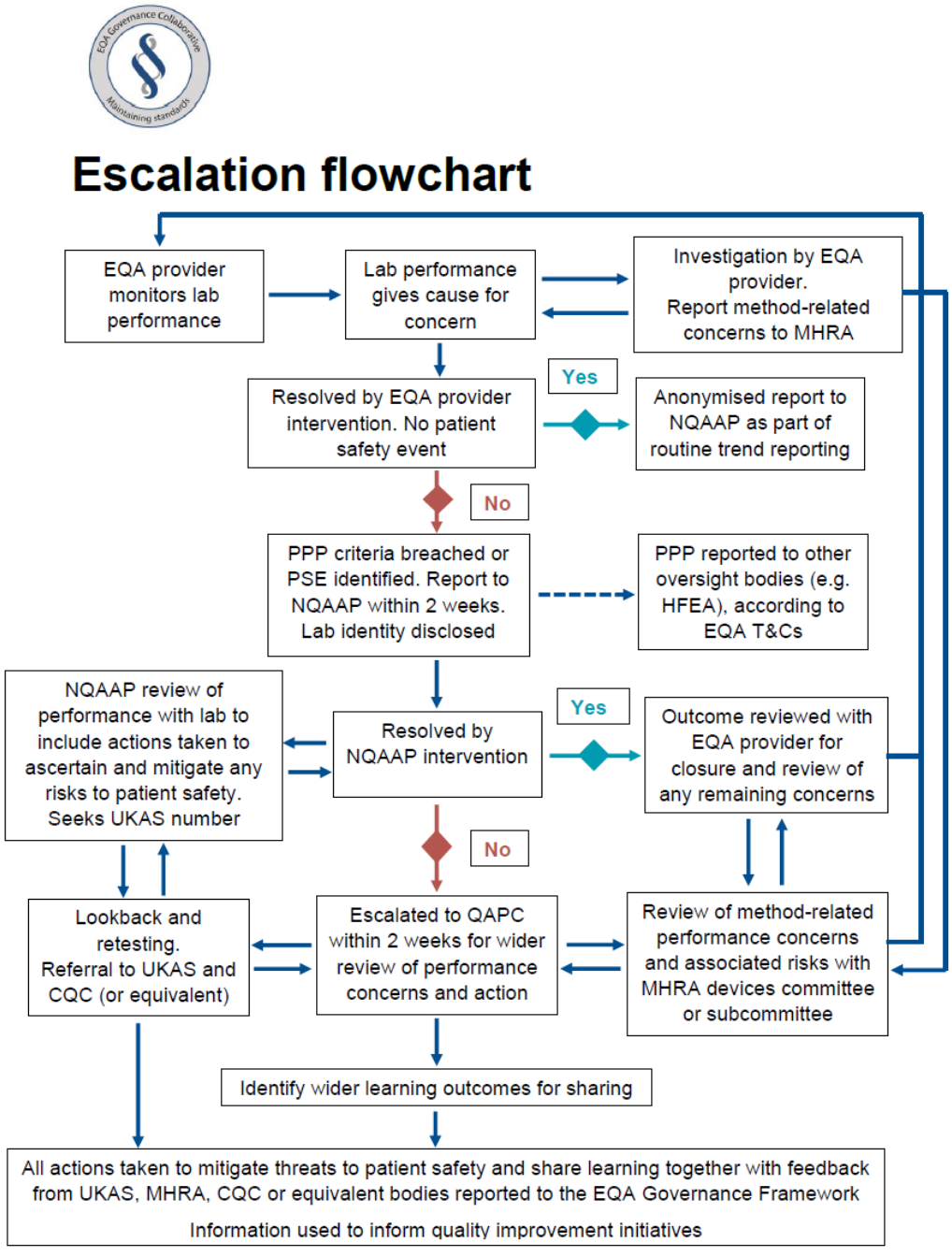
Weqas adheres to the policies and procedures approved by the EQA Oversight Board available from https://www.rcpath.org/profession/patient-safety-and-quality-improvement/technical-eqa.html

The Weqas Director or Deputy Director submits regular reports on participant numbers, new developments and overall Programme performance including laboratory and POCT site poor performance and manufacturer

performance issues to the Chemistry, Haematology and Microbiology Panels. Please note that **reports to the Panel on individual laboratory poor performance although confidential are no longer anonymous for UK participants.**

7.1.1 Poor performance escalation

The following flowchart provides an overview of the poor performance process and describes the expected timeframes for escalation and review of EQA performance concerns.



7.1.2 Definition of Errors and Poor performance

For purposes of reporting to oversight bodies a distinction is made between an escalated error and a non-escalated error.

The distinction between an escalated and a non-escalated error and the criteria for *poor performance* and for *persistent poor performance* are set by the Weqas Director in consultation with the Steering Committee and notified to the relevant NQAAP.

Escalated error will depend on the clinical utility of the test and whether the error may lead to a misdiagnosis, missed diagnosis, inappropriate patient management and/or misinterpretation of the result such that patient safety may be compromised. Any Patient safety event (PSE) is classified as an escalated error.

A non-escalated error is an isolated error or out of consensus performance which is identified by the EQA provider to the participating laboratory where the clinical risk to patient management is low. However, multiple or recurrent non-escalated errors may be indicative of a systematic failure in that laboratory and for that reason may be escalated as poor performance.

Poor performance is therefore defined as a PSE, an escalated error of clinical significance or multiple non-escalated errors within a given timeframe. Poor performance is incurred for the following reasons:

- non-submission of results with no acceptable prior notification to the scheme
- critical analytical error (incorrect result for the patient)
- critical interpretation error, which adversely affects patient management
- no interpretation of the results (where the EQA includes an interpretative element)
- incorrect/inappropriate advice (where these are expected).

A scheme organiser has the right to refer a participant to the designated oversight body if a PSE is identified and/or they judge the error to be sufficiently outwith accepted clinical practice, or there are multiple non-escalated errors that may be indicative of systematic failings.

7.1.3 Poor performance notification

In the event that poor performance is identified as detailed above, the Laboratory or POCT organisation is contacted by the Director/ Deputy Director detailing the breach of acceptable performance and help offered in the form of additional samples, assistance with troubleshooting and an agreed process established. The participant is also made aware that their performance may result in escalation to the NQAAP, including disclosure of their identity. Performance is closely monitored over the next cycle and a failure to return results during this period is regarded as continuation of poor performance and will be automatically deemed as persistent poor performance, unless that non-return has been pre-agreed and authorised by the scheme organiser.

This initial contact, correspondence and action taken are logged by the Director/ Deputy Director (1st SO letter).

A failure to respond to this contact or take any action within 3 months will lead to further contact by Weqas (2nd SO letter) and the NQAAP informed of a potential persistent poor performance by the laboratory.

7.1.4 Persistent poor performance notification

When the performance has not improved after **two contacts,** the laboratory is identified as a persistent poor performer. Within 2 weeks of a laboratory being identified as a *persistent poor performer* the Weqas Director / Deputy will notify the Chairman of the appropriate NQAAP together with a resume of remedial action taken or proposed. The NQAAP Chairman will agree in writing any remedial action to be taken and the timescale and responsibility for carrying this out. .

Correspondence from Weqas staff, NQAAPs and QAPC concerning persistent poor performance will be sent directly to the Head of the laboratory or, in the case of the independent healthcare sector, the Hospital Executive Director.

7.1.5 Non compliance

The NQAAP expects 100% compliance on EQA returns. Compliance is monitored by the Programme Organiser and will be reported to the NQAAP if the return persistently falls below the ideal. Non-compliance will be treated as persistent poor performance.

7.2 Non-Analytical Errors

Please note that requests to amend results following discovery of a transcription error must be submitted in writing to Weqas along with evidence of original analyser results.

It is the responsibility of the participant to notify Weqas as soon as possible that a transcription / transposition error has occurred. Notification must be made within 4 weeks of the results return date. Once documented evidence has been received, the correct result will be entered into the database as soon as possible and an amended report can be viewed via the website. If the participant does not have interactive access, then a hard copy report can be sent if requested. A copy of the transcription error form, and associated documentation, will be kept in the participant's file at Weqas.

8. Evaluation and improvement

There is a documented procedure for monitoring data on participants' satisfaction and complaints which is recorded, reviewed and acted upon. Monthly audits of the Telephone / Communication log are carried out. The results of these audits are documented and brought to the attention of the relevant section head. Audit summaries are presented at the Steering Committee meeting.

The management carry out internal quality audits to verify whether quality activities comply with planned arrangements and to determine the effectiveness of the quality system.

9. Weqas website (www.weqas.com)

The information contained in this Participants manual is also on the Weqas website together with further information on:

About us / Steering Committee	https://www.weqas.com/about/
Services	https://www.weqas.com/services/
News and Events	https://www.weqas.com/news/
Participant Zone	https://www.weqas.com/participantzone/
Learning Zone	https://www.weqas.com/learning-zone/
Resources	https://www.weqas.com/resourcelibrary/
Contact us	https://www.weqas.com/contact/
Subscription charges	https://www.weqas.com/participantzone/subscription-charges/

PARTICIPANTS MANUAL

Weqas

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