UK NEQAS CODE OF PRACTICE (RULES)

Revised in accordance with the Charity's 2016 Articles of Association

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The Code of Practice (Rules) set out the standards of professional conduct and practice expected of Members of the Charity and shall be binding on all Members.

These rules should be read and applied in conjunction with the Articles of Association.

1. DEFINED TERMS

1.1 "**Charity":** means the legal entity known as United Kingdom National External Quality Assessment Service (UK NEQAS). A company limited by guarantee (Company Number: 3012351) and a registered Charity in England and Wales (Charity Number: 1044013).

1.2 **"Board of Trustees":** subject to the Articles, the Board of Trustees are responsible for the management of the Charity's business, for which purpose they may exercise all the powers of the Charity.

1.3 **"Member":** is an external quality assessment (EQA) Scheme recognised by the Board of Trustees as a United Kingdom National External Quality Assessment Scheme in the United Kingdom in accordance with such criteria and such procedures as may be decided upon by the Board of Trustees.

1.4 **"Scheme":** recognised by the Board of Trustees as a United Kingdom National External Quality Assessment Scheme in the United Kingdom in accordance with such criteria and such procedures as may be decided upon by the Board of Trustees from time to time.

1.5 "**Scheme Organiser":** each Scheme, being an unincorporated organisation, shall be a Member of the Charity through the person of its nominated representative (Scheme Director is recognised as an accepted alternative to Scheme Organiser).

1.6 **"Module":** is used to describe an EQA covering an investigation or a group of related investigations.

2. GENERAL OBSERVATIONS

2.1 The Charity expects each Member to ensure that all individuals holding office with that Member comply with and support these Rules.

2.2 Entry into Membership of the Charity is conditional upon the complete and absolute adherence to these Rules and any subsequent Rules made by the Charity.

2.3 No Rule shall be inconsistent with or shall affect or repeal anything contained in the Companies Acts, the Charity's Articles of Association or any rule of law. In the event of any conflict or ambiguity between the Articles of Association and these Rules, the Articles shall prevail.

2.4 The business of the Charity shall be conducted by the Board of Trustees in accordance with the charitable objectives of the Charity. The Board of Trustees is accountable to the Members for implementation of the strategy of the Charity.

2.5 The Board of Trustees are responsible for complying with all UK Company Law and Charity Law in England and Wales, as both directors and trustees of the Charity.

2.6 Scheme participants may be individuals, laboratories or other service providers.

2.7 The Scheme Organiser is responsible for the design and direction of the Member Scheme and accountable to the Board of Trustees for its compliance with the Code of Practice.

3. SCOPE AND PURPOSE OF THE CODE OF PRACTICE

3.1 This Code of Practice governs the behaviour of and provides guidance to Members, the Charity, and the Board of Trustees as to best practice and standards and governs the conduct of behaviour between the parties.

3.2 This Code of Practice operates and is applicable in relation to the Charity's Members (all classes) and the Board of Trustees.

3.3 In examining an individual's or Member's behaviour against this Code of Practice, account shall also be taken of the Charity's Articles of Association.

3.4 This Code of Practice should be read in conjunction with guidance issued from Companies House and the Charity Commission that covers the statutory responsibilities of the persons on the Board of Trustees as Company Directors and Charity Trustees.

3.5 Members shall receive a copy of the Code of Practice and Articles of Association upon admission as a Member of the Charity. Scheme Organisers acting on behalf of Members shall be expected to re-affirm their observance of these Rules on an annual basis through the annual declaration of interest procedure (*see APPENDIX 1: Declaration of Interest Form*).

3.6 An undertaking to abide by this Code of Practice is mandatory to all Members, Scheme Organisers and members of the Board of Trustees. It operates as a contract between the Charity and its Members.

3.7 This Code of Practice may be revised to ensure its effectiveness, compatibility with the Charity's ethos, and adherence and compatibility with the Charity's Articles of Association.

4. MEMBERSHIP PROCEDURES

4.1 Schemes shall be admitted to membership of the Charity when approved by the Board of Trustees in accordance with the Articles of Association of the Charity.

4.2 An application for membership shall be made to the Board of Trustees on an approved application form available from the Charity's Central Office (*see APPENDIX 2: Membership Application Form*). The application shall be accompanied by a signed statement from the Scheme Organiser that the applicant complies with the Code of Practice and the Charity's Articles of Association.

4.3 A Scheme may be admitted as a Member, an Associate Member, or an Affiliate Member (*see APPENDIX 3: Membership Classes*).

4.4 The Board of Trustees shall decline to admit to membership any applicant that fails to fulfil the criteria of this Code of Practice or Articles of Association.

4.5 Only those Schemes that are admitted as Members or Associate Members shall be entitled to use the service mark "UK NEQAS" and the associated logo. Use of the UK NEQAS service mark and logo by Member Schemes and third parties is regulated and governed by prescribed guidelines (*see APPENDIX 4: Use of the UK NEQAS service mark and logo).*

5. SCHEME MANAGEMENT

5.1 The Scheme Organiser shall ensure that the Scheme complies with this Code of Practice and the Articles of Association.

5.2 The Scheme shall be open to all UK providers offering a clinical service for investigations covered by the Scheme. Other participants may be accepted at the discretion of the Scheme Organiser.

5.3 Investigations covered by the Scheme should be selected on the basis of their clinical relevance.

5.4 The Scheme shall be free of any conflict of interest or any perception of the same between the Scheme and its Host organisation.

5.5 The Scheme shall be independent of any manufacturing and marketing interests in equipment and reagents in the field in which it operates

5.6 Any interests in the provision of analytical or other services shall be declared.

5.7 Scheme Organisers shall be qualified to the professional standards appropriate to their job role and proof of such qualifications should be provided.

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

5.9 The Scheme Organiser shall be responsible for copying lists of attendees at Steering Committee/Specialist Advisory Group Meetings to the Charity's Central Office.

5.10 The Scheme Organiser shall monitor those participants failing to maintain acceptable levels of performance.

5.11 The Scheme Organiser shall be responsible for ensuring any unsatisfactory performance in EQA submissions from UK Clinical laboratories are reported according to the relevant oversight and governance processes currently agreed within the UK, and if appropriate for overseas participants.

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

5.13 The Scheme shall operate on a not-for-profit basis. Any operating surplus shall be reinvested in the Scheme.

5.14 There should be no cross-subsidy between host and Scheme in accordance with Department of Health guidelines.

5.15 The Scheme Organiser shall ensure that there are adequate business continuity arrangements in place to ensure the supply of services to participants.

6. SCHEME DESIGN

Member Schemes shall be accredited to ISO 17043 and shall maintain that accreditation. Operating procedures described here should be regarded as minimum standards for the design of Associate or Affiliate Schemes that have not yet achieved accreditation to ISO17043.

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

6.2 The Scheme shall establish performance criteria to enable the timely detection of inadequate performance by participants. Participants who are out of consensus with these performance criteria should be encouraged to improve.

6.3 The Scheme shall aim to improve laboratory performance by education and support for participants and governance structures or stakeholders, to promote continuous improvement and patient safety.

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

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

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

6.7 The Scheme shall provide a clinically appropriate turnaround of results and performance data to participants that enables them to take timely and appropriate action.

6.8 Report format should, as a minimum ensure the following:

6.8.1 A unique Participant Identifier Code is clearly stated on all individual reports;

6.8.2 The performance scores are clearly stated on all participant reports;

6.8.3 The performance criteria for each investigation are clearly stated or shown within the report or point to a website or other published reference.

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

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

7. NOTIFICATION OF A PROPOSED UK NEQAS PILOT MODULE

For Governance reasons with the aim of preventing duplication of work and direct competition by Schemes a formal mechanism is in place to notify the UK NEQAS Board of Trustees of proposed pilot Modules. This does not include one-off surveys or 'pre-pilot' activities.

7.1 Notification

7.1.1 Once approval for a Pilot Module has been given by the appropriate Steering Committee/Specialist Advisory Group, an application shall be made to the Charity's Central Office using the appropriate documentation (*see APPENDIX 5a: Pilot Module Proposal Form*). The Scheme Organiser shall fully complete the form and provide any supporting documentation.

7.1.2 The Proposal Form and any related correspondence shall then be circulated to the members of the Charity with a *Review of Pilot Programme form* (*APPENDIX*5b: Review of Pilot Module proposal form) at least 1 month before the date of the next Board meeting. This form should be completed by all centres and returned to Central Office no later than 2 weeks before the Board meeting.

7.1.3 Any objections should include a statement explaining the reasons for the objection and where possible evidence of direct competition with an existing UK NEQAS programme.

7.1.4 Lack of a response from any centre shall be taken as approval of the application

7.1.5 At the subsequent Board of Trustees meeting, the application shall be reviewed, together with any objections and a decision made as to the granting or rejection of pilot status.

7.2 **Decision.**

7.2.1 If the Board of Trustees rejects the application, it shall state the reason(s) for the decision.

7.2.2 The Charity's Central Office shall notify the Scheme Organiser of the outcome.

7.2.3 Where approval is given, the Charity's Central Office shall inform all members of the outcome.

8. OBLIGATIONS OF MEMBERS THROUGH THEIR SCHEME ORGANISERS

8.1 When appointing a Scheme Organiser, a Scheme shall comply with the Charity's published guidance (*see APPENDIX 6: Guidance on the Appointment of Scheme Organiser).*

8.2 The Scheme Organiser shall keep the Charity informed of significant changes in Scheme's details and activities that affect repertoire, hosting or service delivery.

8.3 The Scheme shall contribute to the operating costs of the Charity's Central Office and the costs of the services provided by the trading subsidiary of the Charity named Pathology Quality Assessment (PQA), through the payment of a precept, as determined by the Board of Trustees.

8.4 The Scheme Organiser shall have reporting duties which shall include the submission of a Financial Return for the purpose of Precept calculations.

8.5 The Scheme Organiser shall submit financial returns including annual accounts as required to the Board of Trustees. These shall be in a standard format and validated by appropriate supporting documentation indicating agreement and acknowledgement by the budget holder. All sources of Scheme incomes shall be disclosed, including any additional income which supports the viability of the Scheme.

8.6 The Scheme Organiser shall ensure that changes to scheme details and other information for publication (e.g. enhancement of services and notice of participants meetings) are made promptly to the Charity's Central Office.

8.7 The Scheme Organiser shall co-operate fully with the development and maintenance of a unified participant identification code database. Information in the database shall not be used by a Member Scheme to the detriment of another Member Scheme.

8.8 The Scheme Organiser shall uphold, support and promote the underlying principles of the Charity as embodied in the Articles of Association and Code of Practice. Scheme Organisers shall play a full part in ensuring that the Charity is a harmonised, participant-responsible and patient-focussed service, and shall not damage the reputation of the Charity as a whole through inappropriate action or inaction.

8.9 The Scheme Organiser shall maintain accreditation to ISO17043 (or standards of recognised equivalence) for any Member Scheme they represent.

8.10 All aspects of the work of a Scheme shall be open to audit conducted by or on behalf of the Charity. The purpose of any such audit shall be to assess the management of the Scheme in its ability to provide a service that complies with the Charity's aims as stated in its Articles of Association and this Code of Practice.

8.11 Where the Scheme Organiser also operates other services including non-UK NEQAS services, the other services shall be financially independent of the Member Scheme. This excludes 'pro-bono' services and works undertaken to support improvement of laboratory medicine quality in for example, resource-poor countries.

8.12 The Scheme Organiser and staff members of Schemes to include members of Steering Committees and Specialist Advisory Groups, shall neither operate nor advise any EQA schemes which are in direct competition with the Charity's Schemes.

8.13 In the event of a Module being developed/provided in collaboration between two or more Schemes, the Scheme Organisers shall have a mechanism to ensure that the results of all participants are reviewed, as a minimum, on an annual basis. Combined performance data shall be presented to the relevant authorities and/or advisory groups.

APPENDICES

1. Declaration of Interest Form;
2. Membership Application Form;
3. Guidance on Membership Classes:
    a. Associate,
    b. Affiliate;
4. Guidance on use of the UK NEQAS Service Mark and Logo;
5. Pilot Modules:
    a. Proposal Form,
    b. Review of Pilot Module proposal;
6. Guidance on the Appointment of Scheme Organiser.