



QUALITY MANUAL

South East England General Histopathology External Quality Assurance (EQA) Scheme

CPA EQA Ref No: 069/0219

QM-HI-EQ-QulMan

This document together with specified procedure manuals represents the Quality Management System of the South East England General Histopathology External Quality Assurance (EQA) Scheme, administered by the Department of Cellular Pathology, Maidstone and Tunbridge Wells Trust. It has been compiled to meet the requirements of the Clinical Pathology Accreditation (UK) Ltd (CPA) External Quality Assurance (EQA) system and appropriate national and international standards. All procedures specified herein are mandatory within the South East England General Histopathology External Quality Assurance (EQA) Scheme.

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AMENDMENT SHEET

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A1				
A2				
A3				
A4				
A5				
A6				

After six amendments, the whole document should be revised and reprinted as a new edition number



PERSONNEL WHO SHOULD READ THIS DOCUMENT

The following grades of staff should ensure they have read all sections of this document:

1. Scheme Facilitator
2. Scheme Organiser
3. Scheme Quality Manager
4. SMC members



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0 GENERAL INFORMATION

0.1 Title of Scheme

The South East England General Histopathology EQA Scheme is administered by the Department of Cellular Pathology, Maidstone & Tunbridge Wells NHS Trust.

The postal address is:-

Cellular Pathology Department
Preston Hall Hospital
Maidstone
Kent
ME20 7NH

Tel: 01622 224060
Fax: 01622 224061

Information on the services provided and contact telephone numbers are available on the CPA web-site (<http://www.cpa-uk.co.uk/>), RCPATH Website (<http://www.rcpath.org/index.asp?PageID=1045>) and in [PD-HI-EQ-PartMan].

0.2 Department of Cellular Pathology, Maidstone and Tunbridge Wells NHS Trust

The Cellular Pathology Department is based at Preston Hall Hospital and is part of the Maidstone and Tunbridge Wells NHS Trust.

0.3 The Service of the South East England General Histopathology EQA Scheme

0.3.1 Aim

To provide an accurate, fair, reliable, efficient, cost effective service of quality assurance and education to all participants of the scheme within the resources available, therefore assuring a high quality diagnostic service to the participants' patients.

0.3.2 Repertoire

The South East England General Histopathology EQA Scheme offers the following services:

- A confidential service for Consultant Histopathologist, Associate Specialist or Locum Consultant individual performance assessment
- A circulation of slides 3 times a year to all participants
- An educational element in each circulation highlighting unusual or bizarre cases
- Active participant involvement in result review via case consultation



- A confidential assessment of each individual's performance, including cumulative reports
- Sympathetic monitoring of poor performance and confidential advice for improvement
- An opt-out scheme for areas not part of a participant's normal practice
- A system for appeal in cases of contentious decisions
- Certification of participation
- Active pursuit of fresh case material
- Case material that is representative of a typical diagnostic workload

The scheme provides services mainly for participants within South East England (Kent, Surrey, Sussex and South London), but consideration is given to applicants outside the area on a case by case basis. The scheme is available to any Consultant Histopathologist or Associate Specialist participating in general routine and specialist Histopathology. Long-term locum pathologists are also able to participate, subject to the payment of the current subscription rate. The scheme predominately circulates prepared slides, but other materials (e.g. photographs) may also be circulated. The scheme requires participants to forward this material in a timely fashion to the next participant on the distribution list.

0.4 The Quality Manual

This Quality Manual describes the Quality Management System of the South East England General Histopathology EQA Scheme. Throughout the text there are references to CPA (UK) Ltd EQA Standards in round brackets e.g. () and to South East England General Histopathology EQA Scheme procedures in square brackets e.g. [] written in fulfilment of these standards.

This Quality Manual (A6) fulfils two functions. It describes the Quality Management System for the benefit of the scheme's own management and staff, and it provides information for users and for inspection/accreditation bodies.

This Quality Manual can be regarded as the index volume to separate volumes of management, clinical, laboratory and quality procedures. The sections of the Quality Manual are arranged so that they equate with the CPA (UK) Ltd Standards (see Table 0.4-1 below). Under the title of each standard there is a brief description of the way in which the South East England General Histopathology EQA Scheme seeks to comply with the particular standard and references are given to appropriate procedures.

The sections of the standards should be seen to relate to each other in the following manner. Section A describes the organisation of a laboratory and its quality management system which uses resources (Sections B, C and D) to undertake pre examination, examination and post examination processes (Sections E, F and G). The quality management system and the examination processes are continually evaluated and quality assured (Section F). The results feed back to maintain and where required



improve the quality management process and to ensure that the needs and requirements of users are met.

Section in the Quality Manual	Section of CPA Standards
3	A Organisation and quality management system
4	B Personnel
5	C Premises and environment
6	D Equipment, materials and reagents
7	E Organisation and design of EQA Scheme
8	F Operation of the EQA Scheme
9	G Communication with participants
10	H Evaluation and Improvement

Table 0.4-1 Section of Quality Manual and equation with CPA(UK) Ltd EQA Standards

1 QUALITY POLICY

The Quality Policy ([A3 Quality policy](#)) of the South East England General Histopathology EQA Scheme is given below and published as separate controlled document. It is displayed within the EQA Office and is e-mailed to each participant

THE QUALITY POLICY OF THE SOUTH EAST ENGLAND GENERAL HISTOPATHOLOGY EXTERNAL QUALITY ASSESSMENT SCHEME

The South East England General Histopathology EQA Scheme is a General Histopathology Interpretive Scheme which is committed to providing a service of the highest quality and shall be aware of, and take into consideration, the needs and requirements of it's members. Membership is open to any Consultant Histopathologist, Associate Specialist or long-term Locum Consultants participating in General or Specialist Histopathology within the region of South East England (covering South London, Sussex, Surrey and Kent). Consideration will be given to applicants outside the area on a case by case basis.

In order to ensure that the needs and requirements of members are met, the Scheme Management will:

- Operate a Quality Management System to integrate the Organisation, procedures, processes and resources that conform to the standards set out by the National Quality Assurance Advisory Panel and those of the Royal College of Pathologists Professional Standards Unit.
- Set quality objectives and plans in order to implement this quality policy
- Ensure that all personnel are familiar with this quality policy to ensure user satisfaction



The South East England General Histopathology EQA Scheme will comply with standards set by CPA (EQA) Ltd and is committed to:

- The maintenance of high standards & continuing compliance with CPA (EQA) standards
- The continuing education of participants
- Ensuring the health, safety and welfare of its staff and participants
- Ensuring the needs of the participants are met and reviewed regularly
- Assessment of participant satisfaction, in addition to internal audit and external quality assurance, in order to produce continual quality improvement.
- Reviewing the SOPs on an annual basis and making appropriate changes
- Maintaining the confidentiality of the participants
- Treating participants fairly, sensitively and without prejudice
- Complying with relevant environmental legislation



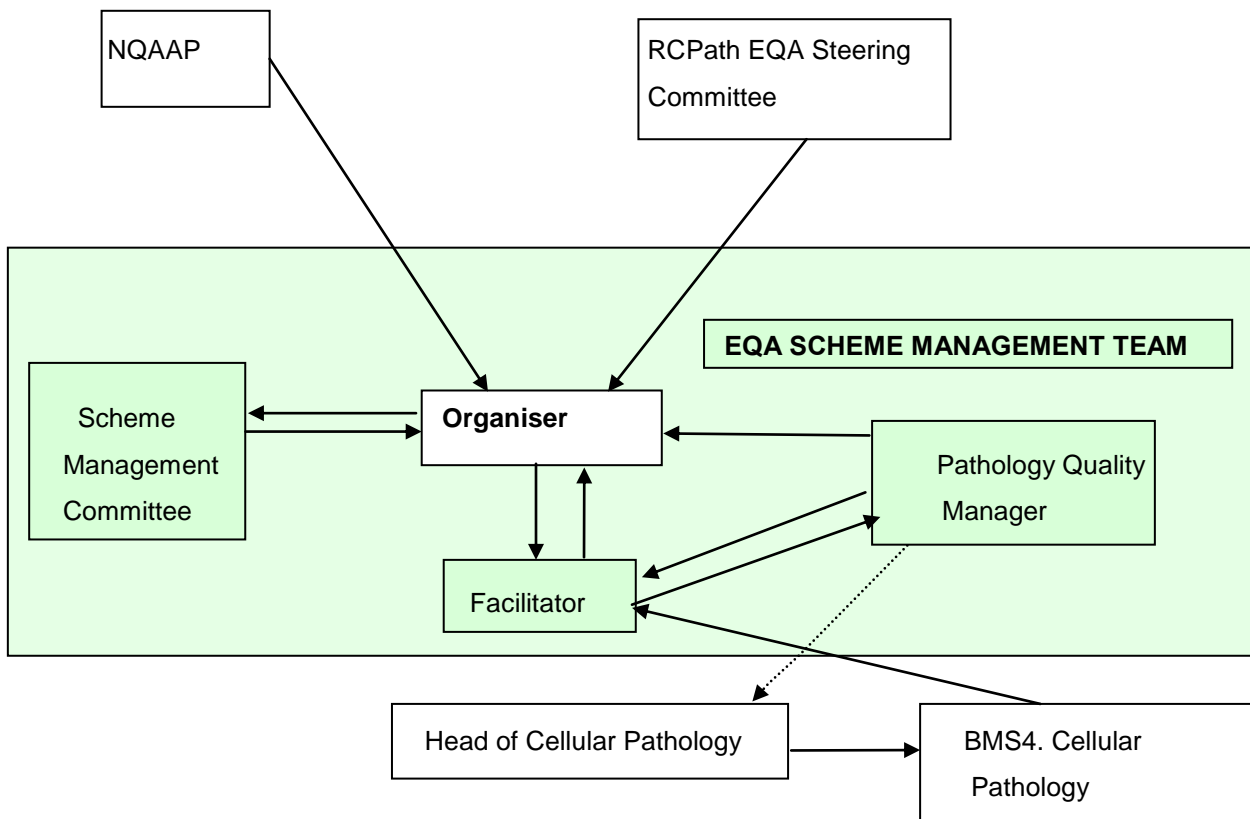
2 ORGANISATION, RESPONSIBILITIES AND AUTHORITIES

2.1 Relationship to the Host Organisation

- The South East England General Histopathology EQA Scheme operates from within the laboratories of the Cellular Pathology Department at Preston Hall Hospital, Maidstone & Tunbridge Wells NHS Trust, with the approval of the Head of Department and the Trust Chief Executive.
- The Cellular Pathology Department at Preston Hall is part of the Pathology Service within the Division of Cancer – Support services of the Maidstone and Tunbridge Wells NHS Trust.

2.2 Organisation and Responsibilities within the South East England General Histopathology EQA Scheme

- The Scheme is organised by a Consultant Cellular Pathologist who is a Fellow of the Royal College of Pathologists (or equivalent). (**B1 Professional direction**). The organisational relationships within are shown below: (**A 1.4**)





- The facilitator performs all of the administration for the Scheme. For the purposes of EQA work, she is accountable and responsible to the Organiser, Dr J Salisbury. (A 1.4). The Scheme facilitator is Mrs G Donald. She is employed by Maidstone & Tunbridge Wells NHS Trust, and is available for two sessions per week for EQA work.
- The Scheme Management Committee (SMC) (A 1.5) meets once a year. (see 4.4.1)
- In relation to the identification and management of persistent substandard performance, the South East England General Histopathology EQA Scheme is guided by, and is accountable to the National Quality Assurance Advisory Panel (NQAAP) for Histopathology and Cytopathology. The Royal College of Pathologists' Steering Committee for EQA in Histopathology and Cytopathology provides guidance with respect to the remainder of the Scheme. For further details, please see <http://www.dh.gov.uk/assetRoot/04/07/21/81/04072181.pdf>.



3 ORGANISATION AND QUALITY MANAGEMENT SYSTEM

3.1 A1 Organisation and management

The organisation and management of the South East England General Histopathology EQA Scheme is described in section 2 of this quality manual

3.2 A2 Needs and requirements of users

The needs of the users are kept under constant review. An open Annual General Meeting is held annually where participants are invited to comment on any aspect of the Scheme Management. Furthermore, the Scheme Management Committee Annual Management Review meeting reviews all queries and complaints and discusses any issues. They are translated into requirements that form the focus of objective setting and planning (A5 Quality objectives and plans) within in the quality management system. Assessment of user satisfaction and complaints (H1 Assessment of user satisfaction and complaints) is conducted on a regular basis and consideration of the findings form part of the annual management review (A11 Management review).

3.3 A3 Quality policy

The Quality policy of the Scheme is detailed in section 1 of this quality manual. The SMC review the policy annually for suitability and effectiveness.

3.4 A4 Quality management system

The components and relationship within the Quality management system are described in section 3 of this Quality Manual and under standards (A5 to A11).

3.5 A5 Quality objectives and plans

The EQA Scheme Management Team defines the quality objectives of the scheme (A5) based on the Scheme quality policy, (A3) in consultation with the SMC and participants, and is responsible for ensuring that plans are made to meet these objectives. The objectives will take account of guidelines from RCPATH, NQAAP, CPA, IBMS, the medical literature and guidance on the retention of tissue. The management review (see 3.11 (A11) below) that is undertaken on an annual basis determines whether the objectives have been successfully completed and provides an opportunity for revising such objectives and plans and for reviewing the effectiveness of the quality management system.

3.6 A6 Quality manual

This standard is fulfilled by the production of this Quality Manual.



3.7 A7 Quality manager

The Quality Manager for the South East England General Histopathology EQA Scheme is Mrs Helen Dasley who works with the Scheme Management Committee to ensure the proper running of the Quality Management System for the South East England General Histopathology EQA Scheme. She is available for half a session a week. The SMC are responsible for the appointment of the Quality Manager for the scheme and that person reports directly to the Organiser

3.8 A8 Document control

This standard is fulfilled by the procedures [LP-HI-EQ-AdminPr], [MP-CP-MT-DocCtrl] and [MI-GN-MT-DocNme] that describes how documents should be controlled in the Scheme.

3.9 A9 Control of technical and quality records

This standard is fulfilled by the following departmental procedures and

- Technical records – made during operation of EQA scheme (E/F/G) [LP-HI-EQ-AdminPr]
- Quality records – made during quality evaluation procedures (H) [MP-CP-MT-RecCtrl]
- Equipment records [MP-CP-MT-EqMan]
- Training and personal records [MP-CP-MT-PersMan]
- Electronic participant records [LP-HI-EQ-AdminPr].

3.10 A10 Control of clinical material

This standard is fulfilled by the procedure [LP-HI-EQ-AdminPr] that describes the control of clinical material by the scheme facilitator including receipt, storage, distribution, retrieval and return.

3.11 A11 Management review

The Scheme Management Committee conduct an annual review, which considers the following items of information

- a) Reports from managerial and supervisory personnel
- b) Assessment of user satisfaction and complaints (H2)
- c) Internal audit of quality management system (H3)
- d) Internal audit of examination processes (H4)
- e) CPA reports (H5)
- f) Reports of assessments by outside bodies



g) Status of preventive, corrective and improvement actions (H6)

h) Major changes in organisation and management, resource (including staffing) or process.

Records are kept and key objectives for subsequent years defined and plans formulated for their implementation.

4 PERSONNEL

4.1 B1 Professional direction

The Scheme is organised by / under the professional direction of a Consultant Histopathologist with an ongoing substantial clinical commitment to routine surgical histopathology (with appropriate scientific training and experience in the field of operation).

Consultant competence is assured by the records of inclusion on the Specialist Register, General Medical Council Licence to Practice, Fellowship of the Royal College of Pathologists by examination and regular competency assessments as part of the South East England General Histopathology Regional External Quality Assurance Scheme.

The current scheme organiser is Dr J Salisbury.

4.2 B2 Staffing

The numbers of staff are adequate for the workload of the Scheme. Deputy staff would be engaged during periods of extended absence. All Biomedical Scientists are fully State Registered. All consultant staff have passed the FRCPATH exam. Regular professional up-dates are attended as required and all Biomedical Scientists and consultants are encouraged to register for Continuing Professional Development.

A document [MF-HI-EQ-Reg] exists which records GMC number of the Organiser and HPC registration numbers of the Facilitator and Quality Manager.

Individuals with specific roles are listed in Table 4.2-1.

The scheme requires the following staff in order to operate.

- Scheme organiser 0.05 WTE
- Scheme facilitator 0.2 WTE
- Quality Manager 0.05WTE
- The EQA Scheme management staff have access to
 - Trust Accountant



- Health and Safety Officer
- Training Officer

The Organiser is Dr J Salisbury BSc MD FRCPath, Consultant Histopathologist, King's College Hospital NHS Foundation Trust and is available for half a session per week. The Scheme is charged by King's College Hospital NHS Foundation Trust for the cost of this work. The Organiser has the approval of the Trusts Chief Executive. There is no deputy Organiser. Urgent queries are passed to a member of SMC.

The Scheme facilitator is Mrs G Donald. She is employed by Maidstone & Tunbridge Wells NHS Trust, and is available for two sessions per week for EQA work. The Scheme is charged by Maidstone & Tunbridge Wells NHS Trust for the cost of this work. There is no deputy facilitator. Work is put on hold during periods of absence and queries are passed to the Organiser.

The Scheme Quality Manager is Mrs H Dasley. She is employed by Maidstone & Tunbridge Wells NHS Trust, and is available for half a session per week for EQA work. The Scheme is charged by Maidstone & Tunbridge Wells NHS Trust for the cost of this work. There is no deputy quality Manager. Work is put on hold during periods of absence.

Scheme Organiser	Dr J Salisbury, BSc MD FRCPath, King's College Hospital NHS Foundation Trust
Scheme Facilitator	Mrs Gillian Donald, MSc FIBMS CSci. Clinical Scientist, Cellular Pathology, Preston Hall, Maidstone and Tunbridge Wells NHS Trust
Equipment Controller	Mr J Withell, Service Manager, Cellular Pathology, Preston Hall, Maidstone and Tunbridge Wells NHS Trust
Training Officer	Miss J Liddell, Cellular Pathology, Preston Hall, Maidstone and Tunbridge Wells NHS Trust (B9)
Health and Safety Advisor	Mr J Withell, Cellular Pathology, Preston Hall, Maidstone and Tunbridge Wells NHS Trust (C5)
First Aider	Mrs H White, Cellular Pathology, Preston Hall,



	Maidstone and Tunbridge Wells NHS Trust
Cellular Pathology Audit Lead	Dr S Saw, Cellular Pathology, Preston Hall, Maidstone and Tunbridge Wells NHS Trust
Cellular Pathology Service Manager	Jim Withell, Cellular Pathology, Preston Hall, Maidstone and Tunbridge Wells NHS Trust
Scheme & Pathology Quality Manager	Mrs Helen Dasley (A7), Pathology, Maidstone and Tunbridge Wells NHS Trust

Table 4.2-1 Personnel with specific roles within Preston Hall Cellular Pathology & the EQA Scheme

4.3 B3 to B7: Personnel management, Staff orientation and induction, Job descriptions and contracts, Staff records, Staff annual joint review

There are Trust employment policies and procedures available electronically on the Trust Intranet which include the recruitment process, orientation, Trust induction, the production of job descriptions and contracts. The Trust has procedures for Staff individual performance reviews, which are performed annually and reviewed at 6-monthly intervals. Staff records are held by the service manager. There is also a Cellular Pathology specific procedure [MP-CP-MT-PersMan]. The pathology directorate training policy [MP-GN-MT-TrnPol] describes a local staff induction programme which is recorded in a personalised record booklet [MF-GN-MT-IndnBk].

4.4 B8 Staff meetings and communication

4.4.1 Management Review Meeting

The Scheme Management Committee (SMC) (A 1.5) meets annually for a Management Review Meeting. Its membership is as follows:

- Four members drawn from current participants (one each from London, Surrey, Sussex and Kent)
- Scheme Organiser
- Scheme Facilitator
- Scheme Quality Manager.

The Terms of Reference for the SMC are as follows:

- To nominate a suitable Organiser to run the scheme and may change the Organiser at any time.
- To review annually the costs of and subscriptions to the scheme.



- To assist the Organiser in encouraging full participation in the scheme by all eligible pathologists in South East England.
- To receive any complaints from participants that cannot be voiced directly to the Organiser.
- To consider the cases of all participants triggering a second action point to
 - (a) satisfy itself that the mechanism of the scheme has functioned fairly
 - (b) resolve any problems capable of local resolution
 - (c) ensure the Organiser passes on all cases to NQAAP.
- To be available for advice and guidance in cases where participants have produced a 1st action point which may cause controversy.
- A 50% attendance at this meeting is required for quoracy on decisions made.

4.4.2 Trust communication

The Trust disseminates information both electronically and in hard copy. Electronic communication may be via the intranet site or by email. The Facilitator has Internet, Intranet and email access. A weekly team communication is sent from the Chief Executive to all staff via email.

Hard copy publications produced and distributed by the trust include:

- Risk Matters – a quarterly health and safety news letter written by the Trust clinical risk manager and sent to the Pathology Quality Manager who then disseminates it to all laboratory managers for departmental notice boards.
- Contact Newsletter – a fortnightly publication distributed to all wards and departments. This contains advertisements, news, and up to date information on Trust-run courses, meetings, and events.
- Recruitment Journal – a fortnightly publication issued and distributed to all Departments by the Trust Recruitment Team advertising vacant positions within the Trust.

4.5 B9 Staff training and education

Training issues are discussed at the Management Review meeting. There are opportunities for further education and training relevant to the needs of the service.

Training objectives are described in the Pathology directorate Training Policy [MP-GN-MT-TrnPol]. State registered Biomedical Scientific (BMS) staff are encouraged to participate in the Institute of Biomedical Scientists (IBMS) Continuing Professional Development (CPD) scheme.

Continuing competence of Consultant medical staff is assured by registration with the Royal College of Pathologists (RCPath) CPD scheme and with membership of relevant External Quality Assurance schemes, Consultant Appraisal, GMC re-validation and regular participation in audit, governance



and clinical risk management processes according to RCPATH and Department of Health guidelines. Records are kept of all training and education by the Medical Director (B6).

Records are kept of all training and education in individuals' portfolios as described in [MP-GN-MT-TrnPol] (B6).

The Preston Hall Cellular Pathology Department has a named training officer (B2) and this individual meets as part of the Training Co-ordinators Group (A1.5) six times per year.

5 PREMISES AND ENVIRONMENT

5.1 C1 Premises and environment

The premises provided are adequate to allow staff to perform required functions in accordance with national legislation and guidelines.

C2 Facilities for staff

All Scheme staff have facilities within the building accommodating the department for changing, secure locked storage for personal possessions, toilets, and a rest area with basic catering facilities and drinking water.

5.2 C3 Facilities for storage

Storage space is sufficient for the adequate maintenance of samples, reagents and records.

- a) Technical records and quality records are held in the Facilitator's Office (A9).
- b) Clinical material is delivered to the facilitator by post according to procedure [LP-HI-EQ-AdminPr] (A10).
- c) Hazardous substances (C5).
- d) Reagents & Consumables (D3).

5.3 C4 Health and safety

The Trust Health and Safety Policies in the Trust and the Local Safety Rules [MP-CP-MT-H&S] are in place to ensure a safe environment for staff, patients and visitors.

The Service manager has responsibility for Departmental Health and Safety. Day to day management of Health and Safety issues is delegated to a named Health and Safety Advisor within the department (B2). The Pathology Health and Safety Committee leads on pathology-wide health and safety issues.

Procedure [MP-CP-MT-H&S] describes Spillage handling



Procedure [MP-CP-MT-H&S] describes the decontamination process (D1).

Chemicals are handled in accordance with [MP-CP-MT-H&S] (D1).

Safe methods for specimen collection, handling, transportation, reception and referral to other laboratories are covered by procedure [MP-CP-MT-H&S]. (E3 to E6).

Risk assessments are performed on all activities and test procedures performed in the department and reviewed annually, using standard forms provided by the Trust and as described in the COSHH, Display Screen Equipment and Risk Assessment procedures found in the Trust Health and Safety policy folder on the intranet. Each test method and activity has a statement on health and safety aspects in the technical Standard Operating Procedure (SOP) for that procedure.

Containment level 2 facilities comply with HSE guidelines and only designated staff are allowed to enter the facility as stated in procedure [MP-CP-MT-H&S].

Containment level 3 facilities comply with HSE guidelines and only designated staff are allowed to enter the facility as stated in procedure [MP-CP-MT-H&S].

Laboratory management ensure through appropriate induction and training that staff are aware of their responsibilities relating to health and safety.

Laboratory management ensure that a safe working environment is provided according to HSE legislation and other relevant legislation.

There is a Trust Occupational Health department available to staff and a confidential counselling service is also provided.

6 EQUIPMENT, INFORMATION SYSTEMS AND REAGENTS

6.1 D1 Procurement and management of equipment

The procurement and management of equipment is described in procedure [MP-CP-MT-EqMan], in accordance with Trust policies. The laboratory equipment meets the demands of the service and is properly validated. The Electromechanical Engineering department has an equipment inventory containing information relating to identification, location, maintenance, servicing, calibration results, failures and repairs of all equipment within the department.

6.2 D2 Management of data and information

The Scheme is committed to meeting its information security obligations to meet the needs of participants with respect to confidentiality, integrity, and availability. The management of Data and



information is described in procedure [PD-HI-EQ-PartMan], [LP-HI-EQ-AdminPr] and [MP-CP-MT-DocCtrl].

6.3 D3 Management of materials

Procedure [LP-HI-EQ-AdminPr] describes EQA case collection, distribution and block return

7 ORGANISATION AND DESIGN OF EQA SCHEME

7.1 E1 Organisation, scope and strategy

The scheme handbook [PD-HI-EQ-PartMan] is e-mailed to each new participant wishing to join the EQA Scheme in accordance with [LP-HI-EQ-AdminPr] and [MF-HI-EQ-DistLst].

7.2 E2 External professional advice

A formally constituted EQA Scheme Steering Committee, known as the Scheme Management Committee (SMC), advises the EQA Scheme Organiser. The constitution of this committee is described in section 2.2. The committee may request changes in the operation of the scheme.

Formal arrangements for communication with the National Quality Assurance Advisory Panel (NQAAP) are described in The Scheme's Participant's Manual [PD-HI-EQ-PartMan].

7.3 E3 Extent of participation

Eligibility of membership of the scheme are described in [PD-HI-EQ-PartMan].

Arrangements for participation, including confidentiality, is described in the participants manual [PD-HI-EQ-PartMan]

7.4 E4 EQA Scheme design: sample distribution and analysis of results

The procedure for distributing samples, including numbers, frequency and nature of sample, is described in [LP-HI-EQ-AdminPr]. Procedures for evaluating the validity of the results are described in [PD-HI-EQ-PartMan].

7.5 E5 Assessment and evaluation of performance

Participation criteria and performance criteria for each examination included in the Scheme is described in [PD-HI-EQ-PartMan]. This document has been approved by NQAAP as described in procedure [LP-HI-EQ-AdminPr]. Procedures for dealing with persistent substandard performance are described in [PD-HI-EQ-PartMan].



7.6 E6 Sub-contractors and collaborators

All material for the EQA Scheme is submitted by participants, as described in procedure [LP-HI-EQ-AdminPr]. All submissions should ideally come from a CPA accredited laboratory as described in [LP-HI-EQ-AdminPr].

8 OPERATION OF THE EQA SCHEME

8.1 F1 Preparation of test items

The procedures for reception, evaluation of suitability, and storage of material for EQA distributions are described in [LP-HI-EQ-AdminPr], in accordance with laboratory Health and Safety rules [MP-CP-MT-H&S].

8.2 F2 Packing and accompanying documentation

The procedures for assembling material for distribution, sample labelling and the documents to include with the distribution are described in [LP-HI-EQ-AdminPr]. Packing and distribution of the materials and documents are described in [LP-HI-EQ-AdminPr] and follow current Specimen Transport regulations.

Document production is described in [LP-HI-EQ-AdminPr]. The procedure for ensuring onward transmission of slides and other materials from one participant to another is described in [LP-HI-EQ-AdminPr].

8.3 F3 Receipt of results

Procedures for receiving results from participants are described in [LP-HI-EQ-AdminPr], including the management of amended results or submissions received after the closing date.

8.4 F4 Data entry and statistical analysis

Results are entered and checked on the EQA management database, as described in [LP-HI-EQ-AdminPr]. The results are analysed and a preliminary result is sent to all participants as described in [LP-HI-EQ-AdminPr]. A case consultation exercise follows, after which consensus agreement of the result is derived. The procedure for invoking the case consultation, and the ensuing result determination, is described in [LP-HI-EQ-AdminPr].

8.5 F5 Reports to participants

The EQA scheme management team recognises the importance of correct, timely, unambiguous and confidential results. Methods for generating, validating and dispatching results to each participant are described in [LP-HI-EQ-AdminPr].



9 COMMUNICATION WITH PARTICIPANTS

9.1 G1 Arrangements for participation

The arrangements for participation are detailed in the participants' manual [PD-HI-EQ-PartMan], sent to all existing participants and prospective new participants. The manual explains the terms and conditions of participation, the practical details of the Scheme design, the mechanism for communication between EQA Scheme staff and participants, the criteria for acceptable participation and performance, then complaints procedure and the responsibilities of the participants. Each participant must agree to the terms within the manual and return a signed document [PD-HI-EQ-PartMan] to the facilitator, pledging their agreement.

9.2 G2 Communication procedures and participant feedback

Procedures for providing technical advice to participants are described in [PD-HI-EQ-PartMan]. Communications to and from participants are recorded and logged, and the action taken is documented. The procedures describing these processes, and the method of filing the communications, are described in [LP-HI-EQ-AdminPr]. All participants are encouraged to participate in the case consultation at the end of every distribution, which allows consensus results to be derived (see 8.4) before reports are sent out evaluating individual performance (see 8.5). Participants are invited to an Annual General Meeting, to meet the EQA Scheme staff face to face and to discuss problems and air ideas for improvement.

10 EVALUATION AND QUALITY ASSURANCE

10.1 H1 Evaluation and improvement processes

The service provided will be continually improved by review of the quality of service. Processes and quality management systems are reviewed at the Annual Management Review (A11). New technical procedures may be introduced within the Scheme after discussion at the Annual Management Review (H2) and formal adoption at the AGM meeting. Proformas and protocols are introduced as required, using section 1.1 of [LP-HI-EQ-AdminPr]. New and established processes are subjected to peer review by the SMC, RCPATH and NQAAP according to [LP-HI-EQ-AdminPr]. These processes and quality management systems are monitored by internal audit as described in procedure [QP-GN-MT-Audit] and discussed at the Annual Management Review meetings (H2).

Reports from external assessment bodies and processes and quality management systems are monitored by review and discussion at Annual Management Review Meetings (H6). The results of the evaluation and improvement processes are evaluated and form part of the next management review (A11).



10.2 H2 Assessment of user satisfaction and complaints

The needs of the participants are kept under constant review. Participant satisfaction surveys (H1) and feedback from internal audits (H3, H4) are discussed at the annual Scheme Management Committee meetings (A11). All complaints and compliments, with resulting actions, are compiled for discussion at the annual meetings. The clinical relevance of the EQA scheme and the reliability of interpretative reports is assessed in conjunction with the SMC. These findings and discussions are translated into requirements that form the focus of objective setting and planning (A5). Consideration of the findings form part of the Annual Management Review (A11).

10.3 H3 Internal audit of quality management system

The quality management system is audited, evaluated, monitored, reviewed and acted upon as described in procedure [QP-GN-MT-Audit].

10.4 H4 Internal audit of EQA Scheme operation

Organisation and design of the Scheme, operation of the Scheme and communication with participants are all subject to internal audit. The process for planning, conducting, evaluating, monitoring and reviewing the audit are described in procedure [QP-GN-MT-Audit]. The results of internal audit are monitored by review and discussion at The Management Review Meetings.

10.5 H5 Quality Improvement

Processes and quality management systems are continually improving and are reviewed at the Annual Management Review (A11). Findings and plans for improvements are detailed in the SMC minutes.

This will be evaluated in the following ways

- internal audit will be performed and results discussed at the management review with completion of audit cycles, formulation of an action plan and implementation of resulting recommendations:
- All non-medical staff will take part in the Continuing Professional Development schemes run by the Institute of Biomedical Science.
- All medical staff will be registered for Continuing Professional Development with the Royal College of Pathologists and for any relevant External Quality Assurance Programmes.
- Non-conformities will be identified and corrective action implemented, as described in [QP-GN-MT-Audit] & [LP-HI-EQ-AdminPr].



- User satisfaction questionnaires will be used to assess performance judged against user expectations. The findings will be discussed at the Management Review meetings and resulting recommendations implemented.
- Internal Quality Control Procedures will be carried out to the highest standards possible and these will be kept under continual review.

