UKAS PROFICIENCY TESTING 7808

Maidstone and Tunbridge Wells NHS Trust

South East England General Histopathology

External Quality Assurance (EQA) Scheme

ISO 17043:2010 Ref No 7808

Quality Manual

RWF-CP-EQA-SOP2

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SIGNIFICANT CHANGES SINCE LAST REVISION

Section	**Change** (Section heading and details)
Front page	New UKAS symbol
throughout	Inclusion of ISO 15189:2022 standards
9.2	Inclusion of availability of Digital images, end of round case discussion
9.4	Wales included
9.5.1	Organiser changed
9.5.4	Amendments to named personnel
9.5.9	Updated competency documentation
9.8	Update on use of digital images for case diagnosis
9.12	Update to content of certificate of participation
10.1	The division is Core Clinical Services
11.9	New section on Process Deviation
11.13	New section on risk management and opportunities

For full document history see QPulse

PERSONNEL WHO SHOULD READ THIS DOCUMENT

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

1. Scheme Manager
2. Scheme Organiser
3. Scheme Quality Manager
4. Scheme Administrator

1 Contents

2 Introduction

2.1 Aim and purpose of document

This Quality Manual together with reference procedures describes the South East England General Histopathology EQA Scheme Quality Management System (QMS) for the benefit of the Scheme's own management and staff, and to provide information for service users and for accreditation and regulation bodies.

This manual has been compiled to meet the requirements of ISO 17043:2010 and 2023 standards.

3 Personnel

3.1 Who should read this document

All Scheme personnel must read this document via Q-Pulse as part of their induction and ensure aware of changes on each review.

3.2 Responsibility

The Scheme Quality Manager (QM) is responsible for the preparation and maintenance of this document and ensuring its availability to all Scheme personnel.

All Scheme personnel are responsible for ensuring they have read the most up to date revision of this document and acknowledged this on Q-Pulse.

3.3 Training requirements

All Scheme personnel undergo training and competency assessment in regards to the basic quality management system coordinated by the quality team.

4 Definitions

- Quality Management System
- Q-Pulse – an electronic QMS utilised to support the delivery of the QMS; modules utilised include Audit, CA/PA, Documents, Assets, Supplier and Analysis module.
- Standard Operating procedure (SOP) – a document established by consensus and approved by an authorised person that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at optimum achievement in a given context.

5 Impartiality

MTW has two policies that all employees are required to comply with to ensure impartiality for service provision which are the Anti-fraud, bribery and corruption policy and the Conflicts of Interests policy and procedure. All registered professionals are bound by their own registrations bodies code of conduct to ensure impartiality.

Impartiality in tenders in assessed through the procurement setting where all individuals involved in the process are required to sign a non-disclosure waiver which will outline if there are any conflict of interests or not. If a conflict of interests is identified; appropriate action will be taken including, where required, removal of said personnel from the tender process.

Impartiality in personnel management is paramount and established within Pathology by having access to different senior managers within the directorate's departments, across the Trust and within the Network for recruitment, HR investigations and management where required. Staff with direct relationships within the directorate are not permitted to line manage directly or indirectly one another to prevent potential bias or presumed bias.

Conflicts of interest can occur within the personnel of the scheme and it is important that these are recognised and handled appropriately with proper procedures put in place.

To identify potential conflicts of interest, each staff member makes a declaration at each Scheme Management meeting, which is recorded. All activities of the Scheme are conducted with impartiality. Any possible conflicts of interest will be discussed within the Scheme Management Committee to implement suitable procedures as required.

Recognised examples of conflict of interest within the scheme include:

1) The Scheme Quality Manager carrying out audits of the scheme's quality management system.

Solution: The Pathology Quality Officer conducts the non-statistical audits

2) The Organiser takes part in the scheme as a participant, giving rise to a possibility of influencing marking. Solution: The "answer" is initially provided by the case submitter and is not made known to the Organiser during case selection. The "answer" is confirmed by consensus of all participants.

6 Confidentiality

The scheme ensures that confidentiality of participants' information is maintained through a variety of mechanisms including a secure areas of work where participant information is not readily accessible to non-scheme personnel and the mandatory annual information governance training and assessment for all staff. This is also part of the standard induction for Pathology personnel outlined in the Pathology staff handbook (RWF-TRAIN-LI3).

The scheme allocates each participant with a unique code and results are submitted using the code. Any communication containing a participant's name is redacted e.g. email is anonymised before passing to the organiser. The Scheme Administrator receives and keeps a record of all communication and responses from participants in a manner that ensures confidentiality. The system is designed to ensure the Scheme Organiser remains unaware of an individual and/or their performance. The numeric code for each participant is held on a password-protected spreadsheet that only the Scheme administrator and the Scheme Manager have access to. The database holding results utilises the participant's code only and is password protected. The Organiser communicates with participants on a personal basis by their code number only, via the scheme administrator. This will usually be via email but on occasion may be via postal letter. There are defined circumstances when confidentiality will be breached. These are clearly described in the participant manual [RWF-CP-EQA-SOP1] and in the Administration SOP [RWF-CP-EQA-SOP3].

7 Legal entity

MTW is the legal entity that is held responsible for the Scheme and its activities; this is led by the Trust board, comprising of the Chairman, non-executive Directors, Chief Executive Officer (CEO), and Executive Directors.

8 Ethical conduct

The ethical conduct expected of Scheme staff is outlined in the Pathology staff handbook (RWF-TRAIN-LI3) received by all personnel at induction documents and within the equality and diversity Trust training which is mandatory for all staff to undertake.

9 Organisational and Management Structure

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

The postal address is:-

Cellular Pathology Department
Maidstone Hospital
Hermitage Lane
Maidstone
Kent
ME16 9QQ

Tel: 01622 225738

Email: mtw-tr.EQA@nhs.net

Website: http://www.mtw.nhs.uk/gps/pathology/se-england-general-histopathology-eqa-scheme/

Information on the services provided are available on the UKAS web-site https://www.ukas.com/search-accredited-organisations/ and in the Participant's manual [RWF-CP-EQA-SOP1], which is issued to all participants when revised, and to all new participants when joining the scheme.

The Cellular Pathology Department is based at Maidstone Hospital, within the pathology service of the Maidstone and Tunbridge Wells NHS Trust.

9.1 Aim of scheme

- To provide an accurate, fair, reliable, efficient, cost effective UKAS accredited external quality assurance programme to all participants of the scheme within the resources available, therefore assuring a high quality diagnostic service to the participants' patients
- To provide an educational process for the Continuing Professional Development (CPD) of consultant histopathologists
- To facilitate laboratories of participating members to fulfil ISO 15189:2022 requirements regarding participation in interlaboratory comparison programmes.

9.2 Purpose of Scheme

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 glass slides three times a year to all UK based participants
- Digital images of the same circulation slides available to all participants including overseas participants
- An educational element in each circulation highlighting unusual or bizarre cases
- Active participant involvement in result review via case consultation and end-of round case discussion
- 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 organ systems not covered by a participant's normal practice
- A system for appeal in cases of contentious decisions
- Certification of participation
- Award of RCPath-accredited CPD points
- Fresh case material in each round
- Case material that is representative of a typical diagnostic workload

9.3 Design overview

The Scheme is an interpretive scheme, requiring participants to determine a clinical diagnosis from microscopic examination of a single histological H&E glass slide, in combination with provided clinical details. The clinical details may or may not include the results of immunohistochemistry and/or special stains. All slides have been made from previously diagnosed clinical material and have been submitted by participants, either voluntarily or by request. The scheme requires participants to forward this material in a timely fashion to the next participant on the distribution list.

There are three circulations a year. Each round consists of 10 cases representative of different organ systems within a routine non-specialised histopathology workload, and two slightly more difficult/ unusual cases of educational value which are not scored. Participant may exempt themselves from organ systems that are not reflective of their clinical practice. Diagnoses are free text and differential diagnoses are permitted. Results are reviewed via case consultation to establish the assigned value. The individual results are compared with the assigned value established by consensus and scored.

Individual performance is monitored over time for poor performance. Confidentiality is maintained throughout.

Scanned images of the circulated material are available via the scheme website and may be referred to at any time during or after the circulation. The images are particularly useful for case consultation and for review on receipt of personal results.

9.4 Eligibility

The scheme provides services mainly for participants within South East England (Kent, Surrey, Sussex, London and Essex) and Wales, 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.

9.5 Personnel

9.5.1 Professional direction

The Scheme is organised under the professional direction of a Consultant Histopathologist with an on-going substantial clinical commitment to routine surgical histopathology (with appropriate scientific training and experience in the field of operation). This ensures accountability and informed objectives and decision making.

Consultant competence is assured by 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.

It is the responsibility of the Organiser to:

- Ensure that there are appropriate numbers of staff with the required education, training and competence to provide a scheme that meet the needs & requirements of the users.
- Ensure the implementation of the quality policy
- Implement a safe working environment in compliance with good practice and applicable requirements
- Relate and function effectively with applicable accrediting & regulatory agencies (e.g. UKAS), appropriate administrative officials, the healthcare community and the patient population serviced, and providers of formal agreements, when required.
- Ensure the selection and monitoring of scheme suppliers.

- Provide professional development programmes for scheme staff and opportunities to participate in scientific and other activities of professional laboratory organisations.
- Oversee implementation of Quality Management System including performance and quality improvements, complaints & suggestions and contingency plans.

Some duties and responsibilities are delegated to the Scheme Manager and Scheme Quality Manager although ultimate accountability for the overall operation and direction of the Scheme remains with the Scheme Organiser.

The current scheme Organiser is Dr Nipin Bagla, MBBS, DCP, MD, FRCPath, PG cert genomics.

9.5.2 Staffing

The scheme has identified the managerial and technical personnel with the necessary authority, resources and technical competence required to perform their duties. The following staff are required in order to operate:

- Scheme Organiser 0.5 PA (2 hours per week)
- Scheme Manager 0.2 WTE
- Quality Manager 0.05 WTE
- Scheme Administrator 0.48 WTE

The Manager, Administrator and Quality Manager are employed by Maidstone & Tunbridge Wells NHS Trust.

The Organiser is contracted to Maidstone & Tunbridge Wells NHS Trust.

Scheme staff are guided professionally by the Royal College of Pathologists, and the Institute of Biomedical Scientists where appropriate.

All staff within the team meet formally at the Scheme management meeting to discuss the planning and operation of the scheme. The Terms of reference for this meeting is RWF-EQA-TOR1. Between the formal meetings, there are informal meetings or communications among two or more members of the team as the need arises.

9.5.3 Qualifications

The minimum levels of qualification and experience necessary for the key positions above are defined in person specifications appended to job descriptions. See Scheme Administration SOP [RWF-CP-EQA-SOP3]. The GMC number of the Organiser and HCPC registration number of the Manager is recorded [RWF-CP-EQA-REC1]

9.5.4 Employment and Contracts

The Trust Human Resources department issues contracts of employment to MTW staff members. Maidstone and Tunbridge Wells NHS Trust charge the scheme for the personnel.

The Organiser has the approval of his/her main employer and MTW Trust Chief Executive. The Scheme Organiser contract is issued by MTW. There is no deputy Organiser. In their absence, urgent queries are passed to another member of the Scheme Management Committee. Where advice is required, the Scheme Advisory Panel (SAP) will be consulted. The SAP terms of reference are documented in RWF-CP-EQA-F52. The mechanism for appointment and replacement of the Scheme Organiser is described in the Scheme Administration SOP [RWF-CP-EQA-SOP3]

The Pathology General Manager appoints the Quality Manager.

The Cellular Pathology Head BMS appoints the Scheme Manager.

The Scheme Manager appoints the Scheme Administrator.

The Scheme Management Committee appoints the Organiser. The tenure of the Organiser is described in the Organiser's job description [RWF-CP-EQA-F18].

Scheme Organiser	Dr Nipin Bagla, MBBS, DCP, MD, FRCPath, PG cert genomics, Cellular Pathology, William Harvey Hospital, East Kent Hospitals University Foundation Trust
Scheme Manager	Gillian Donald, MSc FIBMS CSci. Clinical Scientist, Cellular Pathology, Maidstone Hospital, Maidstone and Tunbridge Wells NHS Trust
Scheme Quality Manager	Helen Dasley, MSc, Cellular Pathology, Maidstone Hospital, Maidstone and Tunbridge Wells NHS Trust
Scheme Administrators	Louise Knowler, Cellular Pathology, Maidstone Hospital, Maidstone and Tunbridge Wells NHS Trust

The EQA Scheme management staff have access to a Trust Accountant, Trust Statistician and support from the following staff

TABLE 9.5-1 PERSONNEL WITH SPECIFIC ROLES WITHIN MAIDSTONE HOSPITAL CELLULAR PATHOLOGY & THE EQA SCHEME:

Equipment Controller	Julie Cooke, Head BMS, Cellular Pathology, Maidstone Hospital, Maidstone and Tunbridge Wells NHS Trust
Training Officer (Cellular Pathology)	Clare Locke, Cellular Pathology, Maidstone Hospital, Maidstone and Tunbridge Wells NHS Trust
Health and Safety Advisor	Julie Cooke, Head BMS, Cellular Pathology, Maidstone Hospital, Maidstone and Tunbridge Wells NHS Trust
Cellular Pathology Head BMS	Julie Cooke, Head BMS, Cellular Pathology, Maidstone Hospital, Maidstone and Tunbridge Wells NHS Trust
Cellular Pathology Quality Lead	Rosebud Rusike, Cellular Pathology, Maidstone Hospital, Maidstone and Tunbridge Wells NHS Trust

There is an agreement with the Cellular pathology department for the ad-hoc use of these staff [RWF-CP-EQA-REC16] and any others with specific roles (e.g. First Aider, Fire marshal etc.)
In the event of staff absence, the document [RWF-CP-EQA-F12] lists suggested deputies.
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. There are job descriptions for all personnel, describing duties and responsibilities, prepared using Trust templates. Copies of job descriptions are stored on the Pathology QPulse database. The job description for the Scheme Organiser is RWF-CP-EQA-F48. The job description for the Scheme Quality Manager is RWF-CP-EQA-F56. The job description for the Scheme Manager is RWF-CP-EQA0-F49. The job description for the Scheme Administrator is RWF-CP-EQA-F50. Review of the job description forms part of appraisal.

9.5.5 Personnel management

Staff are an essential asset to the effective running of the scheme. Personnel management ensures that staff contribute fully and effectively to the service whilst receiving fair and consistent treatment from management. Personnel employed by the host Trust are managed following Trust and Departmental Personnel Management policies and procedures [RWF-CP-SOP7]

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. Induction into the department is recorded via RWF-TRAIN-F1. Induction into the Scheme is via the Scheme competency [RWF-TRAIN-COMP-CP-EQA2].

The Trust keeps its personnel informed by disseminating information both electronically and in hard copy. Electronic communication may be via the intranet site or by email. The Scheme Manager, Scheme

Administrator and Scheme Quality Manager have Internet, Intranet and email access. A weekly team communication is sent from the Chief Executive to all staff via email. Other publications are published periodically, distributed via email from the Trust communications team and accessible from the Trust intranet.

9.5.6 Roles of Personnel within the scheme

Only individuals who meet the minimum specifications described in the Job Specification will be employed by the scheme. Once all training has been completed and competencies have been signed off, staff members will be deemed to be authorised to carry out their duties within the scheme.

The scheme authorises the following personnel to perform specific tasks

Selection of appropriate proficiency test items	Scheme Organiser
Planning of proficiency testing scheme	Scheme management committee
Sampling checks	Scheme manager and Scheme organiser
Result entry on Participant Response Software (Response)	Scheme Manager
Participant and case administration on dedicated software (Genpath)	Scheme Administrator
Stability & Homogeneity determination	Scheme Manager
Determining Assigned Value	Case contributor
Determining uncertainties of the measurands of the proficiency test item	Scheme participants via initial result submission and subsequent case consultation
Preparation of proficiency test items	Case contributor and scheme administrator
Handling & distribution of proficiency test items	Scheme administrator
Statistical Analysis (routine)	Scheme Quality Manager
Evaluation of performance of proficiency testing participants	Scheme Manager
Monitoring of performance of proficiency testing participants	Scheme manager
Evaluation of performance of proficiency testing participants	Scheme Organiser
Opinions & Interpretations	Scheme Organiser
Authorisation of issue of proficiency testing reports	Scheme Manager

9.5.7 Staff records

Maintenance of accurate staff records is an essential part of personnel management. Staff records are held by the Trust Human Resources department. Occupational Health Records are kept by the Occupational Health Department. Staffing records required for the immediate management of the Scheme are held in the Scheme Manager's office in a lockable filing cabinet. There is also a Cellular Pathology specific procedure [RWF-CP-SOP7], used by the EQA scheme. The pathology directorate training policy [RWF-TRAIN-SOP1] describes a local staff induction programme which is recorded in a personalised record booklet [RWF-TRAIN-F1].

Content and location of	CENTRAL	LOCAL

staff record		
Personal details	✓ Full record	✓ Limited record
Employment details	✓ Full record	✓ Limited record
Job description	✓	✓
Terms and conditions of employment	✓	✓
Record of staff induction and orientation		✓
Record of attendance at fire lectures	✓	✓
Record of education and training including continuing professional development		✓
Relevant educational and professional qualifications	✓ Full record	✓ Limited record
Certificate of registration, if relevant	✓	✓
Absence record	✓	✓
Accident record	✓	
Record of annual appraisal	✓	✓
Occupational health record	✓	
record of disciplinary action	✓	✓

9.5.8 Staff appraisal

The Trust has procedures for Staff appraisals, which are performed annually. Appraisals of the Scheme Manager and Scheme Quality Manager in relation to EQA Scheme duties are incorporated into their main post appraisals, carried out by their line managers and informed by a report from the Scheme Organiser. Trust appraisal documentation is used. The Scheme Manager conducts the appraisal of the Scheme Administrator. Objectives with respect to the education, training and skills for each staff member involved with the operation of the Scheme may be identified at appraisal or as part of the objective setting process at Annual Management review. The identification of training needs and training provision are described in the Pathology Staff Training procedure [RWF-TRAIN-SOP1].

The Organiser is a contracted role. Performance is reviewed via the Scheme Management Committee. Unresolved unsatisfactory performance would lead to termination of the contract.

9.5.9 Training and Competency

Training objectives are described in the Pathology directorate Training Policy [RWF-TRAIN-POL1]. Further information can be found in the EQA Scheme Training Policy [RWF-CP-EQA-POL2] and Cellular Pathology Training Procedure [RWF-TRAIN-SOP-CP1]. The training programme, training record and objective measures of competency are described and recorded on the Scheme competency form [RWF-TRAIN-COMP-CP-EQA2] and completed in compliance with RWF-PATH-LI129. Training is tailored to the job role. Access to continuing

education and training is important for all staff and participation in Continuing Professional Development schemes is supported as a method of achieving this for relevant members of the Scheme Team.

Training and education shall be in accordance with guidelines from the relevant professional and registration bodies. Training issues are discussed at the Management Review meeting. All staff shall be given the opportunity for further education and training in relation to the needs of the scheme and their professional development.

Resources for training and education include access to library and information services, access to a conveniently situated quiet room for private study, staff attendance at meetings and conferences and financial support. Records of training and education are kept by relevant line mangers. Each member of staff has a training and development portfolio.

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

Records are kept of all training and education in individuals' portfolios as described in [RWF-TRAIN-POL1].

The Maidstone Hospital Cellular Pathology Department has a named training officer and this individual is a member of the Pathology Training Co-ordinators committee. Ongoing competency is recorded on RWF-TRAIN-COMP-CP-EQA4 and there is a question bank RWF-TRAIN-COMP-CP-EQA3 to test competency.

9.6 Equipment, Accommodation & Environment

9.6.1 Premises and environment

The EQA scheme moved into the newly-built Cellular Pathology department in 2011. The premises provided are adequate to allow staff to perform required functions safely and efficiently, in accordance with national legislation and guidelines. The administrative area of the Scheme is on a separate floor to the laboratories. 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. Some of these facilities are shared with the Microbiology department.

9.6.2 Environmental Conditions

Slide production is performed in the laboratories of participants, including the histology laboratory of the host Trust. Those laboratories that are ISO15189:2012 or ISO15189:2022 accredited have environmental monitoring systems in place to ensure environmental conditions do not compromise the quality of the slides. Prepared slides are extremely stable. Any slides received from non-accredited laboratories are checked on receipt to ensure suitability.

9.6.3 Access Control

Entry to the cellular pathology department is via swipe entry. Visitors are asked to buzz through to histology on arrival when they are then escorted to their destination. Slides submitted to the EQA scheme and in preparation for distribution are kept in a separate locked facility, accessible only by the Scheme administrator and the Scheme manager. This prevents participants from the host Trust from being able to gain an unfair advantage. Computers are removed (if laptops), shut down or locked when not in use.

9.6.4 Storage conditions

The provision of sufficient storage space, under the correct conditions, is important in maintaining the integrity of samples and records. Storage facilities are described in Scheme Administration SOP [RWF-CP-EQA-SOP3] and is in accordance with all relevant legislation, regulations and guidelines.

a) Confidential information and documents in hard copy relating to the current circulation are locked securely in a filing cabinet dedicated to the EQA scheme. Technical records and quality records of a non-confidential nature are on open shelves in the EQA Scheme administration area or held electronically within the Pathology electronic quality management database (QPulse).

b) Clinical material is delivered to the EQA Office by post according to procedure [RWF-CP-EQA-SOP3]. Slides awaiting circulation are stored in a separate locked facility within the Molecular Pathology laboratory, which is temperature monitored and accredited to ISO 15189:2012

c) Reagents and Hazardous substances are not stored by the EQA scheme. Work involving hazardous substances is subcontracted to the host laboratory, (accredited to ISO 15189:2012)

d) Stationery and other consumables are stored in the EQA office area.

e) Archived Documents and records in hard copy are stored at Chatham Archive and a record of stored items is documented t [RWF-CP-EQA-F34].

9.6.5 Separation of incompatible activities

The laboratories are on a different floor of the building to the administrative area of the EQA scheme. The scheme does not prepare slides from blocks. Slides submitted to the EQA scheme are kept in a separate locked storage area to diagnostic slides.

9.6.6 Procurement and management of equipment

The procurement and management of equipment is described in procedure [RWF-CP-SOP4], in accordance with Trust policies, and covers the following:

- Assessment and justification of need
- Selection & acceptance
- Training
- Maintenance, service and repair
- Planned replacement and disposal
- Record of equipment failure and subsequent corrective action

The 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, electrical safety checks, failures and repairs of all equipment within the department.

An inventory of equipment is also held by the Cellular Pathology department [RWF-CP-SPREAD6] and includes the computers used by Scheme staff.

9.6.7 Health and safety

The Trust Health and Safety Policies in the Trust and the Local Safety Rules [RWF-CP-SOP6] are in place to ensure a safe environment for staff 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. The Pathology Health and Safety Committee leads on pathology-wide health and safety issues.

Procedure [RWF-CP-SOP6] describes Spillage handling

Procedure [RWF-CP-SOP6] describes the decontamination process.

Chemicals are handled in accordance with [RWF-CP-SOP6].

The control of clinical material including receipt, storage, distribution, retrieval and return is described in procedure [RWF-CP-EQA-SOP3].

Safe methods for specimen collection, handling, transportation, reception and referral to other laboratories are covered by procedure [RWF-CP-SOP6]. 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 [RWF-CP-SOP6].

Containment level 3 facilities comply with HSE guidelines and only designated staff are allowed to enter the facility as stated in procedure [RWF-CP-SOP6].

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

Scheme 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.

Health and Safety audits of the working area are conducted annually by cellular pathology staff.

9.7 Design of the proficiency testing scheme

9.7.1 Planning

The fundamental design of the scheme was originally based on the RCPath publication of 1998 "Recommendations for the development of histopathology / cytopathology EQA schemes" at its inception in 1999. It is designed and planned to be a cost-neutral service and has subsequently been modified and adapted to meet the requirements of the participants, meet accreditation standards (previously CPA EQA, currently ISO 17043:2010 and transitioning to ISO17043:2023) and the guidance in the 2017 RCPath publication "Principles and guidance for interpretive external quality assessment schemes in laboratory medicine" (G153).

The Scheme is accredited by UKAS to ISO 17043:2010 and is an RCPath-approved interpretive EQA scheme for general histopathology.

The Scheme Management committee plan the processes affecting the quality of the Scheme and ensure that they are carried out in accordance with described procedures via documented scheme management meetings. Advice on the planning may be sought from or given by the Scheme Advisory Panel, Royal College of Pathologists or the participant membership, but the decisions remain the responsibility of the Scheme Management Committee and the Scheme Organiser.

The objectives of the Scheme are described in section 9.1 above

The purpose of the scheme is outlined in section 9.2 above

The basic design of the scheme is outlined in section 9.3 above. Further detail is available throughout this document.

Eligibility and conditions for participation are described in the participant manual [RWF-CP-EQA-SOP1]. Details of how to submit results are also in the participant manual. Arrangements for participation, including confidentiality, are described in the Participant's Manual [RWF-CP-EQA-SOP1]. There is an option to opt out of participation in some diagnostic categories, where these are not part of routine workload. The criteria and method of opt out is described in the participants manual [RWF-CP-EQA-SOP1].

Current membership is approximately 175 participants and membership numbers are reviewed at the annual management review to ensure viability of the scheme (including statistically meaningful evaluation of performance) and to identify any additional resource required.

Case material reflects the clinical service delivered by the participants and is submitted from participants. The submitting participants declare whether the case is eligible for inclusion as a scoring case or is for educational purposes. After technical checks, the Organiser selects anonymised scoring cases from each different organ system available, and two educational cases. The detailed mechanism by which case material is selected for distribution is described in the Administration SOP [RWF-CP-EQA-SOP3].

The material used for EQA slides is all of human origin, and due regard is paid to ethical considerations. Anonymity, confidentiality and control of clinical material, as described in the Administration manual RWF-CP-EQA-SOP3 ensure that distributed slides do not contain patient names or originating laboratory numbers, slides are only utilised for the scheme or for subsequent training purposes, and records are kept of all returned slides to enable tracing of missing slides.

9.7.2 Preparation of proficiency test items

The procedures for reception, evaluation of suitability, batch integrity and storage of material for EQA distributions are described in the Administration manual [RWF-CP-EQA-SOP3], in accordance with laboratory Health and Safety rules [RWF-CP-SOP6].

9.7.3 Homogeneity & stability of test items

Homogeneity and stability considerations are described in Statistical Design SOP [RWF-CP-EQA-SOP4]. The initial onus for ensuring homogeneity is on the contributor of the case, as described in the Participant Manual [RWF-CP-EQA-SOP1]. Further checks for ensuring homogeneity & stability of the sample prior to distribution are conducted by the EQA scheme management team as described in [RWF-CP-EQA-SOP3]. Slides are retained securely within the on-site EQA storage system for a period of 30 years, which is a period less than that at which quality may start to decline.

9.7.4 Statistical Design

The Scheme is an interpretive scheme. The statistical design of the scheme has been designed to meet the challenges of textual data (clinical diagnoses), synonyms and partial synonyms which may convey subtle additional information, a vast range of possible diagnoses, uncertainty in responses, uncertainty of the “true” diagnosis and unequal importance in diagnostic error, in line with RCPath *Principles and guidance for interpretive external quality assessment schemes in laboratory medicine.* RCPath (2017)

The scheme allocates numeric scoring to the proffered diagnoses, based on popularity and consensus. Personal scores are calculated based on the score allocated to their proffered diagnosis(es) and the confidence of their diagnosis(es). Personal scores are ranked to identify poor performers and accommodates those participants who have exclude themselves from answering all cases in a round, if this reflective of their clinical practice. The full description of the statistical design is in the Scheme Statistical Design SOP [RWF-CP-EQA-SOP4] and the statistical methods have been approved by the host Trust statistician.

9.7.5 Assigned values

The assigned value is a clinical diagnosis, determined from microscopic examination of a single histological H&E slide, in combination with provided clinical details which may or may not include the results of immunohistochemistry. Diagnoses are free text, rather than selected from a pre-prepared list, to reflect clinical practice. The scheme allows for differential diagnosis, whereby a participant assigns a weighting to one or more suggested diagnoses for a case, indicating the confidence of their answer. There are many synonyms and partial synonyms for a diagnosis within histopathology and the scheme accommodates this via a consultation stage to determine the diagnoses to combine to produce the differential list of diagnoses. The popularity of each diagnosis is calculated based on the number of participants suggesting that diagnosis and the confidence score allocated to the diagnosis.

The case is suitable for scoring if one of the diagnoses has a popularity value of at least 75% and that diagnosis matches the diagnosis submitted at the time of case contribution.

Safeguards are in place to ensure the original case diagnosis is not revealed prior to result release, so that it is not possible for any participant, particularly the organiser or participants within the host Trust, to gain an advantage from early disclosure. The measures in place are described in the Administration SOP [RWF-CP-EQA-SOP3].

Mechanisms are in place to handle cases where the reported diagnosis provided at the time of case submission is different to the highest-scoring assigned value. The Scheme Statistical Design SOP [RWF-CP-EQA-SOP4] gives detailed information on the calculations to determine the assigned values.

9.8 Choice of method or procedure

H&E-stained histological glass slides are circulated. These have been prepared from diagnostic material and represent the clinical material found in routine histology laboratories. Slides should be examined by light microscope using magnification of up to x400. Digital images of the slides are also available via the scheme website. Guidelines for using the digital images for case diagnosis RWF-CP-EQA-LI23 has been published on the Scheme website. These images may also be used for case consultation, review after personal results have been received and for the end-of-round case discussion meeting.

9.9 Operation of the proficiency testing scheme

9.9.1 Instructions for participants

Prior to a round starting, notice is sent to all participants by email, informing them of when they may expect the proficiency material to be in their department, as described in Administration SOP [RWF-CP-EQA-SOP3] Accompanying the email is

- A circulation list, indicating participants in the relevant department and details of onward transmission dates and addresses
- A proforma response sheet containing case histories and the date for return of diagnoses.

The slides are sent, accompanied by instructions, dates and addresses for forward circulation. See Administration SOP [RWF-CP-EQA-SOP3].

9.9.2 Proficiency test items handling and storage

Scheme management recognise the importance of identification and segregation of proficiency test items prior to distribution, such that they are not contaminated or degraded. The method of receipt and storage of proficiency test items is described in [RWF-CP-EQA-SOP3]

9.9.3 Packing, labelling and distribution of proficiency test items

The procedures for assembling material for distribution, sample labelling and the documents to include with the distribution are described in [RWF-CP-EQA-SOP3]. Packing and distribution of the materials and documents are described in [RWF-CP-EQA-SOP3] and follow current Specimen Transport regulations.

Document production is described in [RWF-CP-EQA-SOP3]. The procedure for ensuring onward transmission of slides and other materials from one participant to another is described in [RWF-CP-EQA-SOP3].

9.10 Data analysis & evaluation of proficiency testing scheme results

The proper management of data and records is essential for the provision of the Scheme. 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 [RWF-CP-EQA-SOP1], [RWF-CP-EQA-SOP3] and [RWF-CP-SOP8].

9.10.1 Data analysis and records

With the exception of the result data, Scheme data is stored on networked servers that are backed up nightly by the Host Trust Information Technology team. Backup files are retrievable by contact with the Trust IT team. This includes the data held on QPulse. The Result software is a standalone product that is manually backed up by the Scheme Manager prior to each data manipulation, in accordance with [RWF-CP-EQA-LI19]

Procedures for receiving results from participants, are described in [RWF-CP-EQA-SOP3], including the management of amended results or submissions received after the closing date. Procedures for evaluating the validity of the results are described in [RWF-CP-EQA-SOP1] and [RWF-CP-EQA-SOP3].

Results are entered checked on the EQA management database and technical checks are made to ensure the validity of data entry, data transfer, statistical analysis and reporting. as described in [RWF-CP-EQA-LI19] and [RWF-CP-EQA-SOP3]. The results are analysed. There are mechanisms to detect suspicion of collusion. A preliminary list of proffered diagnoses is sent to all participants as described in [RWF-CP-EQA-SOP3]. A case consultation exercise follows, after which consensus agreement of a differential diagnoses list for each case is derived. The procedure for invoking the case consultation, and the ensuing result determination, is described

in [RWF-CP-EQA-SOP3]. A proportional score is allocated to each differential diagnosis, based on the popularity of each diagnosis. This is automatically calculated by the result database software but the calculation is described in the Statistical Design SOP [RWF-CP-EQA-SOP4]. The calculation is checked manually periodically. The advantage of this system is that there is no bias from the organiser or any other self-appointed expert in the allocation of marks, in the determination of the "correct" answer.

Various checks are made during scheme operation to ensure proficiency test items are suitable. Pre-distribution checks include technical quality checks, and homogeneity checks, as described in [RWF-CP-EQA-SOP3]. In the event that distributed material is subsequently found to be unsuitable, there are mechanisms for withdrawal and/or replacement.

9.10.2 Evaluation of performance

Personal scores are calculated based on the value assigned to the diagnosis given, and the confidence score allocated by the participant to that diagnosis. Where more than one diagnosis has been offered, the score for each diagnosis is calculated and added together. This is automatically calculated by the result database software but the calculation is described in the Statistical Design SOP [RWF-CP-EQA-SOP4]. For each case, a maximum score of 1.0 is possible. This is attained if the participant submitted a single diagnosis that is the same as the diagnosis with the highest popularity score. The scores for each case answered are totalled and calculated as a percentage of the total number of eligible scoring cases for that participant. A participant who has excluded themselves from an organ system and has therefore answered only 9 cases has an equal opportunity to attain 100% as one who answers 10 cases. The personal scores are ranked (highest to lowest). All those with the same score are ranked equally. The participants with scores in the bottom 3% are identified as poor performers. Data entry checks and checks of the slides issued to those participants in the bottom 3% are conducted to ensure validity of the results, as described in Administration SOP [RWF-CP-EQA-SOP].

Personal scores and the ranking is calculated automatically by the result database software but the method of calculation is described in the Statistical Design SOP [RWF-CP-EQA-SOP4]. The calculation is checked manually periodically by Scheme Management and the mechanism for doing this also provides a contingency in the event of software failure. See RWF-CP-EQA-LI12. The evaluation of performance is not subcontracted.

Participation criteria and performance criteria for each examination included in the Scheme is described in [RWF-CP-EQA-SOP1]. This document has been approved by RCPath EQA Steering Committee as described in procedure [RWF-CP-EQA-SOP3]. Poor performance is monitored over subsequent rounds and triggers action points if the criteria are met. See Participant Manual [RWF-CP-EQA-SOP1] and Administration SOP [RWF-CP-EQA-SOP3] for further details.

9.11 Reports

The EQA scheme management team recognises the importance of correct, timely, unambiguous and confidential results.

The reports are generated from the result software and include the results of individual participants and anonymised result performance for all participants, so that individual performance can be compared to group performance. Details of result content are described in Statistical Design SOP [RWF-CP-EQA-SOP4].

Methods for generating, validating and dispatching results to each participant are described in [RWF-CP-EQA-SOP3]. The Scheme Manager authorises the release of the results, which are dispatched by the Scheme Administrator.

Results from each case are reviewed at the Annual General Meeting, to which all participants are invited. Some of the cases may be presented by the original contributors.

Where it is necessary to issue an amended report, it will include a unique identified (subsequent version number to that most recently dispatched), a reference to the original and most recently dispatched version and a statement concerning the reason for the amendment. All instances of the requirement to issue an amended report generate a non-conformance. Report issue is monitored as part of the turnaround time data and recorded on the Scheme Dashboard, which is reviewed at Scheme Management meetings. If reports are not issued within 7 calendar days of the target turnaround time, a non-conformance is raised, as described in Administration SOP [RWF-CP-EQA-SOP3]

9.12 Communication with participants

Procedures for providing technical advice to participants are described in [RWF-CP-EQA-SOP1]. 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 [RWF-CP-EQA-SOP3]. All participants are encouraged to participate in the case consultation at the end of every distribution, which allows consensus results to be derived (see **Error! Reference source not found.**) before r eports are sent out evaluating individual performance). 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. The Scheme Advisory Panel holds a meeting immediately prior to the AGM. Terms of Reference for this can be found at [RWF-EQA-TOR4].

Certificates of participation are issued to all participants who qualify. The certificate states participation in all aspects of the scheme including case submission, exemptions, case consultations and attendance at end-of-round case discussions. Details of certificate qualification and issue are described in Administration SOP [RWF-CP-EQA-SOP3].

10 Management requirements

10.1 Organisation

The South East England General Histopathology EQA Scheme operates from within the department of Cellular Pathology at Maidstone Hospital, Maidstone and Tunbridge Wells NHS Trust, with the approval of the Clinical Director and the Trust Chief Executive.

Personnel are managed in accordance with host organisation policies and procedures

The Cellular Pathology Department at Maidstone Hospital is part of the Pathology Directorate within the Division of Core Clinical Services of the Maidstone and Tunbridge Wells NHS Trust.

This scheme takes full responsibility to carry out its proficiency testing operations in such a way as to meet the requirements of ISO/IEC 17043:2010(E) and to satisfy the needs of its participants and regulatory authorities and those of the host Trust, Maidstone and Tunbridge Wells NHS Trust (MTW).

The management system of the Scheme covers work conducted by Scheme personnel and conducted by subcontractors, whether on site or at a different facility.

The Scheme Administrator and Scheme Quality manager are dedicated entirely to Scheme operation. All other staff have additional roles. The Scheme Quality Manager is bank staff employed by MTW, having previously been Quality Manager for the Pathology directorate. The Scheme Manager is employed as a Clinical Scientist in the Molecular Pathology department of Cellular Pathology, MTW. The Organiser may or may not be a member of MTW staff and has duties as a clinical histopathologist in their employing Trust. The responsibilities for Scheme provision are outlined below:

Officer	1st line management. Responsible to	2nd line management. Responsible to	Main Responsibilities
Scheme Organiser	RCPath EQA Steering Committee / CPPP	MTW Directorate Clinical Director	• Chair meetings • Promotion of Scheme • Select cases for rounds • Correspondence with participants • Represent Scheme at RCPath meetings • Identify key speakers for meetings • Identify regional representatives
Scheme Manager	Scheme Organiser	Cellular Pathology	• Management of scheme

		Service Manager Pathology General Manager	• Purchase & maintenance of equipment • Promotion of Scheme • Process complaints & non-compliances • Maintenance of database • Data analysis and Maintenance of confidentiality
Scheme Quality Manager	Scheme Manager	Scheme Organiser	• Maintenance of quality management system • Audit scheduling & conduct • Document management • Statistical analysis • Maintenance of confidentiality • QMS database maintenance
Scheme Administrator	Scheme Manager	Scheme Organiser	• Administration of scheme • Organisation of slide circulation • Record keeping • Arrange meetings • Communication with participants • Maintenance of confidentiality • Website maintenance

The Scheme is directed by a Consultant Cellular Pathologist (Scheme Organiser) who is a Fellow of the Royal College of Pathologists (or equivalent).

The Administrator and Manager perform all of the administration for the Scheme.

For the purposes of EQA work, the Manager is accountable and responsible to the Organiser.

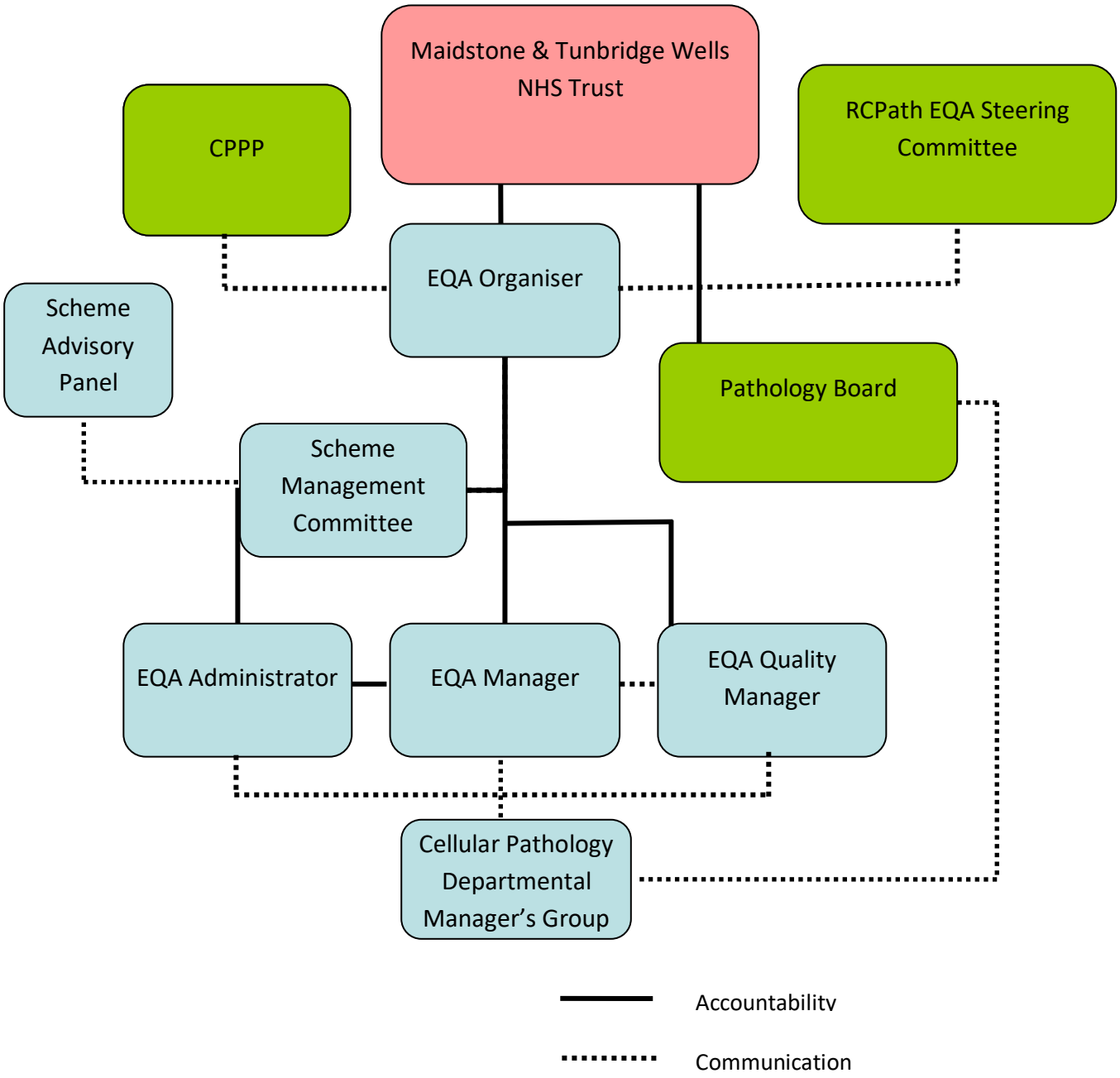
The Administrator is responsible to the Manager and accountable to the Organiser.

The Scheme Organiser, Scheme Manager, Scheme Quality manager and scheme administrator are the Scheme Management Committee. The Terms of Reference for the group are defined in (RWF-EQA-TOR1].

A formally constituted EQA Scheme Advisory Panel (SAP) advises the EQA Scheme Management Committee. The constitution of this group is described in the Terms of Reference for the group (RWF-EQA-TOR4]. The committee may request changes in the operation of the scheme but has no managerial responsibility for the scheme.

Formal arrangements for communication with the RCPath EQA Steering Committee and the College Professional Performance Panel (CPPP) are described in The Scheme's Participant's Manual [RWF-CP-EQA-SOP1]. Copies of the annual report for the scheme are sent to the RCPath EQA Steering Committee as a formal communication agreement. This is shared with participants at the Annual General Meeting.

The organisational relationships within are shown below:



The Organiser is responsible for selecting appropriate proficiency test items, planning the proficiency testing scheme, conducting measurements to determine stability and homogeneity of the measurands of the proficiency test times, evaluating the performance of the proficiency testing participants, giving opinions and interpretations and authorising the issue of proficiency testing reports. The Organiser is responsible for ensuring the scheme has managerial and technical personnel with the necessary authority, resources and technical competence required to perform their duties.

The Manager is authorised to manage the scheme and conduct technical validation on the suitability and homogeneity of the test material, operate the data processing system and conduct statistical analysis. The Manager ensures that there are staff with the minimum levels of qualification and experience necessary for the key positions within the scheme and ensures those qualifications are met.

The scheme administrator is authorised to prepare, handle and distribute proficiency test items. The Administrator organises and takes minutes at all scheme meetings and participates in audit with the Quality Manager along with the amendment and distribution of documents.

The scheme Quality Manager has responsibility and authority for ensuring that the quality management system is implemented and followed at all times.

The Scheme Management Committee (SMC) meets quarterly.

The Scheme Advisory Panel (SAP) meets once a year.

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 RCPath EQA Steering Committee and the College Professional Performance Panel (CPPP) for Cellular Pathology.

10.2 Management system

11 The Quality Manual

This quality manual describes the QMS within South East England General Histopathology EQA Scheme for the benefit of the Scheme's own management and staff and provides information for participants, their employers and for regulatory/accreditation bodies.

The sections of the quality manual are arranged so that they provide statements to describe how the scheme complies with the ISO 17043:2010 and 2023 standards and reference is made to any corresponding procedure (where applicable). The quality manual can be regarded as the index volume to separate volumes of management operational and quality procedures.

Scheme policies and procedures are founded on Pathology policies and procedures which in turn are founded on MTW policies (available on Trust governance Q-Pulse module via intranet) e.g.

- Information Governance Policy
- People policies manual
- Waste policy and procedure for the management of healthcare
- Incident management policy and procedure
- Concerns and complaints, policy and procedure for management o
- Risk Management policy and procedure
- Social Media policy and procedure

11.1.1 The Quality Manual

All policies, procedures and instructions are documented and stored electronical on the Pathology Quality Management System database (QPulse) and are distributed to appropriate personnel electronically. These cover all aspects of scheme operation and quality.

The Quality Policy of the South East England General Histopathology EQA Scheme [RWF-CP-EQA-POL1]. is published on the Scheme webpage http://www.mtw.nhs.uk/gps/pathology/se-england-general-histopathology-eqa-scheme/ It is authorised by the Scheme Organiser.

The overall objectives of the quality policy are reviewed during management review.

The management system is audited to ensure implementation. Improvements are identified either through audit or at review meetings or via staff or participant suggestions. Actions are identified to implement the improvements. Systems are identified to monitor the impact.

All staff within the Scheme recognise that the participants of the scheme are essential to the successful operation of the scheme. Without participant contribution of cases and active involvement in case consultation, the scheme could not function as designed. It is therefore imperative that all staff within the scheme respond to customer requirements, within statutory and regulatory requirements, in an appropriate manner.

The management system is defined by the Quality Policy and described in the Quality Manual. Standard Operating Procedures describe the administration and operation of the scheme and the statistical design. Instructions give detailed information about specific aspects of the process. There

are references to Cellular Pathology and Pathology documents, where these apply to the South East England General Histopathology EQA Scheme.

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 0.05 WTE. The Scheme Manager appoints the Quality Manager.

Scheme management recognise that the integrity of the Scheme is paramount to maintain the reputation of the Scheme and the Host Trust and to maintain accreditation status. Significant changes to the management system are assessed and controlled via the change control process RWF-PATH-SOP13.

The EQA Scheme Management Committee define the quality objectives of the scheme based on the Scheme quality policy, in consultation with the Scheme advisory panel and participants, and is responsible for ensuring that plans are made to meet these objectives. The objectives take account of guidelines from RCPath, CPPP, ISO, IBMS, the medical literature and guidance on the retention of tissue. The management review (see **Error! Reference source not found.** below) that is undertaken o n 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.

11.2 Document control

11.2.1 General

Administration SOP [RWF-CP-EQA-SOP3] and the pathology wide QPulse Document Module SOP RWF-PATH-27 describe how documents should be produced and controlled in the Scheme.

All documents are administered within the pathology electronic Quality Management database (QPulse). Preparation of draft documents is conducted, and authorisation is recorded within QPulse.

Documents from external sources such as regulations, standards, guidelines and manuals are registered on QPulse, and uploaded on QPulse if electronically available. The location of hard copy documents is recorded within QPulse.

11.2.2 Document approval & issue

All documents issued as part of the management system are reviewed and approved for use by authorised personnel prior to use. Templates are available to assist with content and structure. After preparation and before issue the documents will be edited for clarity and accuracy before authorisation by relevant members of the Scheme Management team. The lead approver is stated on every controlled document.

The master list is the document list on QPulse, which records current revision status and the distribution of documents. Printed copies are not generally produced unless for a service-critical process. The process for removal of hard copy obsolete documents is described in the pathology wide QPulse Document Module SOP RWF-PATH-27

Documents are distributed to relevant personnel within MTW electronically via QPulse. There is a process for distributing documents to relevant people who are not within the Pathology department of MTW, described in the Administration SOP [RWF-CP-EQA-SOP3] and recorded on the subcontractor register RWF-CP-EQA-F39.

All documents are uniquely identified and include date of issue, revision number, page, numbering and the lead approver of the document. Documents are reviewed in accordance with the programme of review stated in the pathology wide QPulse Document Module SOP RWF-PATH-27. Invalid or obsolete documents are promptly removed from issue and made obsolete.

11.2.3 Document changes

Changes to documents are reviewed and approved by the individual with the same role as the person who performed the original review and approval.

Changes may result from changes to reference documentation, audit findings, non-conformities or agreed planned changes by Scheme Management committee and may be recorded as change requests within the document file of QPulse, prior to review.

Changes are recorded in the "significant changes" section of SOPs and in the "change details" section of the QPulse document record. A list of all change requests made and the revision in which they were implemented is generated within the electronic database.

Hand amendments of documentation is not permitted.

There is an instruction for how to revise documents within the pathology wide QPulse Document Module SOP RWF-PATH-27.

11.3 Review of requests, tenders & contracts

The process for tenders and contracts follows host Trust policies and procedures and is described in the pathology SOP "Purchase and monitoring of supplies and services." [RWF-PATH-SOP18]

The Scheme management committee reviews tenders and contracts at annual management review, to ensure the requirements are adequately defined, documented and understood, there is capability and resource to meet the requirements and that the proficiency testing scheme is technically appropriate.

Requests to deviate from Scheme protocols (ie. Participation from outside regional area or to participate at differently level or frequency from that normally offered) are discussed by Scheme Management Committee to evaluate the impact to Scheme operation and resources.

The conclusion of the discussions are recorded in the meeting minutes. Participants or other customers will informed of any changes or deviation in contract or agreed proficiency testing scheme design.

11.4 Subcontracting services

The main subcontracted activities are the provision of case material, submitted by participants, and slide scanning. Some Trust staff are also utilised for various activities, as described in 9.5.4 above.. All case submissions should ideally come from an ISO 15189 accredited laboratory as described in [RWF-CP-EQA-SOP3]. Where this is not possible, there are records of checks made to ensure compliance.

The Scheme management committee is responsible to the participants and other customers for subcontracted work.

The register of subcontractors and subcontracted activities is documented in RWF-CP-EQA-F39.

11.5 Purchasing services & supplies

The proper procurement and management of equipment and supplies ensures that the scheme can fulfil the needs and requirements of users. All purchasing of equipment and supplies by the scheme follows MTW procedures and are obtained from sources approved by MTW Trust.

The process for selection of services and supplies follows host Trust policies and procedures and is described in the pathology SOP "Purchase and monitoring of supplies and services." [RWF-PATH-SOP18]. The procurement of equipment is described in the pathology SOP "equipment procurement and management" [RWF-PATH-SOP15] and in the cellular pathology SOP [RWF-CP-SOP4]

Consumables such as stationery is ordered directly by the Scheme Administrator on the approval of the Scheme Manager in accordance with [RWF-CP-SOP10].

Procedure [RWF-CP-EQA-SOP3] describes EQA case collection & distribution.

11.6 Service to the customer (participant)

The needs of the participants are kept under constant review.

All complaints and compliments, with resulting actions, are compiled for discussion at regular meetings and consideration of the findings form part of the annual management review. These are translated into requirements that form the focus of objective setting and planning within in the quality management system.

Participant satisfaction surveys of participants are conducted to inform decision making and to set quality objectives to improve the scheme.

The clinical relevance of the EQA scheme and the reliability of interpretative reports is assessed. These findings and discussions are translated into requirements that form the focus of objective setting and planning. Consideration of the findings form part of the Annual Management Review.

Participants have a regional representative who sits on the Scheme Advisory Panel (SAP). This panel meet with the Scheme Management Committee annually but may contact the scheme on behalf of a participant at any time.

An open Annual General Meeting is held annually where participants are invited to comment on any aspect of the Scheme Management.

The scheme administrator is the point of contact for all queries.

The processes for managing participant feedback is described in Administration SOP [RWF-CP-EQA-SOP3]

11.7 Complaints & appeals

The participants manual [RWF-CP-EQA-SOP1] describes the processes for making a complaint or appeal.

Processes for managing and responding to participant complaints is described in Administration SOP [RWF-CP-EQA-SOP3]. Complaints are assessed for degree of seriousness. In the event that there is a complaint about the professional behaviour of a member of Scheme Management, this will be escalated to the Directorate Clinical Director for investigation and follow the Trust formal complaints procedure. Complaints are recorded within the non-conformance module of QPulse. All complaints are reported to Pathology Board meetings by the Quality Manager and reviewed as part of the annual management review.

Changes to the scheme resulting from a complaint will be agreed by Scheme Management Committee and after appropriate change management processes, appropriate documentation is amended, approved and reissued.

Appeals are managed in accordance with Administration SOP [RWF-CP-EQA-SOP3].

11.8 Control of Non-Conforming work

Any aspect of scheme activities found not to conform to its own procedures or the agreed requirements of its participants will be recorded and investigated as described in the Administration SOP [RWF-CP-EQA-SOP3] and Pathology Identification, reporting and management of non-conformities and continual quality improvement (RWF-Path-SOP17). Sources of non-conformity include audit findings, complaints and errors. Following root cause analysis, corrective and preventive

actions will be determined. The CAPA module of QPulse is utilised (RWF-Path-SOP22). The non-conformity is closed by the Scheme Manager, following approval from the Scheme Quality Manager.

In the event that actions require recall of results, recall of test material or re-issue of poor performance notifications, all relevant participants will be notified as soon as possible.

11.9 Process Deviation

On rare occasions, circumstances may arise where there is deliberate intent to deviate from documented procedures. Such deviations should be documented within the CAPA module of Qpulse and the causes investigated. Any identified improvements should be incorporated into the quality management system.

11.10 Improvement

11.10.1 Quality Improvement

Processes and quality management systems are continually improving and are reviewed at the Annual Management Review. 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 [RWF-CP-EQA-SOP3].
- 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.

11.10.2 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. Terms of reference can be found at [RWF-EQA-TOR2]. New technical procedures may be introduced within the Scheme after discussion at the Annual Management Review and formal adoption at the AGM meeting. Proformas and protocols are introduced as required, using section 1.1 of [RWF-CP-EQA-SOP3]. New and established processes are subjected to peer review by the SMC, RCPath and CPPP according to [RWF-CP-EQA-SOP3]. These processes and quality management systems are monitored by internal audit as described in procedure [RWF-PATH-SOP3] and discussed at the Annual Management Review meetings.

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

11.11 Corrective Actions

Remedial actions, taken at the time the non-conformance is first raised, are recorded with completion dates.

Investigation follows, which is recorded with a completion date.

Corrective actions arising from non-conformities (from either incidents or audit) are determined following root cause analysis. The EQA scheme follows the Pathology SOP for identifying, recording and managing non-conformities RWF-PATH-SOP17. The scheme manager determines and implements the corrective actions. Target dates for the actions are recorded. The Quality Manager monitors the corrective actions to evaluate their effectiveness. Where appropriate, audits are scheduled to evaluate the success of the implemented corrective actions. The actions are evaluated as part of the Annual Management Review.

11.12 Preventive Actions

Preventive actions arise either from quality improvements (QINs), or as part of a non-conformance (NCN) and identify improvement opportunities and causes of potential nonconformities. Actions are identified, implemented and monitored. New systems of work identified to prevent the likelihood of non-conformities are incorporated into the procedures as applicable. The EQA scheme follows the Pathology SOP for identifying, recording and managing quality improvements RWF-PATh-SOP17. All preventive actions are recorded on QPulse and are monitored by the Scheme Quality Manager. The actions are evaluated as part of the Annual Management Review.

11.13 Risks and Opportunities

The identification and management of risks, impact assessments and mitigation is described in Pathology Quality Risk SOP RWF-Path-SOP20. Risks should be assessed as part of the change control process (RWF-PATH-SOP13).

11.14 Control of records, data and information

Records, data and information are an essential component of the functionality and quality of the Scheme. The process by which they are generated, managed and stores is described in the following departmental procedures

- Technical records – made during operation of EQA scheme [RWF-CP-EQA-SOP3] and [RWF-PATH-SOP32]
- Quality records – made during quality evaluation procedures [RWF-PATH-SOP32]
- Equipment records [RWF-CP-SPREAD6]
- Training and personal records [RWF-PATH-SOP32]
- Electronic participant records [RWF-CP-EQA-SOP3] and [RWF-PATH-SOP32].

RWF-CP-EQA-LI1 is a summary list of all the records and gives guidance on location, retention times, indexing mechanism and archiving location. This includes technical records and quality records. The records may be in hard copy or maintained electronically.

The Scheme administrator has primary responsibility for ensuring that all technical records are stored securely.

The Scheme Quality manager has primary responsibility for ensuring that all quality records are stored securely.

All data entries, changes and checks of records made in hard copy are initialled and dated at the time the record is made, by the staff member concerned.

Electronic records made in QPulse are signed off by electronic signature.

Access to the Result Database is via password and access is restricted to the Scheme Administrator and the Scheme Manager.

11.15 Surveillance and Internal Audits

Internal audit provides evidence to demonstrate that the quality management system has been effectively established, implemented and maintained, and that the Scheme is being operated in accordance with agreed procedures and the standards of ISO17043:2010.

The management system is audited, evaluated, monitored, reviewed and acted upon as described in procedure [RWF-PATH-SOP3]. The Scheme Quality Manager plans an audit schedule to cover the technical procedures and proficiency test item preparation, storage and distribution, as well as reporting activities for the operation of a proficiency testing scheme. This is generally over a two-year period. Internal audit is conducted by either the Scheme Quality Manager (statistical analysis) or the Pathology Quality Officer (operational activities), both of whom are trained in audit.

The audits are recorded within QPulse and include the activities, areas and items covered and any non-conformances or quality improvements.

The results of internal audit are evaluated at annual management review.

11.16 Management reviews

The Scheme Management Committee (SMC) meets quarterly for a Management Review Meeting. This includes the Annual Management Review (AMR)

Membership and purpose of this meeting are described in the Terms of Reference. See RWF-EQA-TOR1.

Preparation and conduct of the AMR is described in the Scheme Administration SOP [RWF-CP-EQA-SOP3]

The annual review considers the following items of information:

a) Reports from managerial and supervisory personnel

b) Assessment of user satisfaction and complaints, including advisory group feedback

c) Outcome of Internal audit

e) Reports of assessments by outside bodies

f) Changes in the volume and type of work

g) Status of preventive, corrective and improvement actions

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

i) Continuing suitability of quality policy and Scheme procedures

The records from the AMR are recorded [RWF-EQA-MIN1] and key objectives for the subsequent years defined and plans formulated for their implementation.

The Scheme Manager reports EQA scheme issues, comments, complaints to the monthly Cellular Pathology Departmental Managers Group meetings.