# South East England General Histopathology EQA Scheme Standard Operating Procedures

UKAS PROFICIENCY TESTING 7808

# Participant Manual

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**Significant changes since last revision**

| Section | Change |
|---|---|
| Various | Minor Procedural Amendments:<br>• New case submission transport instructions [Section 2.1]<br>• Effects of exemption status on scoring [Section 2.3.3]<br>• Recommended response documents [Section 2.5]<br>• Share point documents not accepted [Section 2.5]<br>• Authenticity statements required for responses [Section 2.5]<br>• Email correspondence [section 2.5]<br>• 1st and 2nd Action point referrals [section 3.1 and 3.2] |

Personnel who should read this document:

**All participants** should ensure they have read the whole of this document before participation in the Scheme. New participants should **return the Participant Manual agreement form to the EQA Scheme office** to indicate agreement with the contents of this document.

Should your agreement with a previous version of this document already be held by the EQA Office, we will assume continued agreement with any updates unless we hear from you within one week of distribution.

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

# 1 GENERAL DESCRIPTION OF THE SCHEME

This is a glass slide and digital image Histopathology Interpretive EQA Scheme. It is for General Histopathology and it covers all organ systems seen in a routine department. It is a consensus-based scheme approved by the Royal College of Pathologists and based on the guidance "Principles and guidance for interpretive external quality assessment schemes in laboratory medicine" RCPath 2017 (G153). The scheme is UKAS accredited to ISO17043:2010 standard (General requirements of proficiency testing), which fulfils ISO 15189:2022 standard 6.2.2 Examination of Interlaboratory comparison materials. Digital slide images for the current circulation and previous circulations are available via the Scheme website https://www.mtw.nhs.uk/gps/pathology/se-england-general-histopathology-eqa-scheme/.

## *1.1 Aims and Objectives of Scheme*

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.

Our objectives are to ensure the smooth and efficient operation of the Scheme as described, by compliance with ISO 17043:2010 (Conformity assessment — General requirements for proficiency testing) standards. Participation in an interpretive scheme accredited to ISO 17043:2010 fulfils the ISO 15189:2022 (Medical laboratories – requirements for quality and competence) standard 6.2.2 (examination of interlaboratory comparison materials).

## *1.2 Scheme Organiser*

The scheme Organiser is a Consultant Cellular Pathologist and a Fellow of the Royal College of Pathologists.

The current Organiser is Dr Nipin Bagla. He is employed by East Kent Hospitals University Foundation Trust but is contracted to work for the scheme for half a session (0.5 PA) per week. The Scheme is charged by Maidstone and Tunbridge Wells NHS Trust for the cost of this work. The Organiser has the approval of both Trusts Chief

Executive. There is no Deputy Organiser. The Manager will forward queries to a member of the Scheme Advisory Panel (SAP) at times when the Organiser is unavailable for a protracted period of time. The Scheme Management Committee appoints the Organiser.

Contact: Dr Nipin Bagla, Consultant Pathologist, Cellular Pathology Dept, Maidstone Hospital, Hermitage Lane, Maidstone, Kent. ME16 9QQ Tel: 01622 225738 E-Mail: nipin.bagla@nhs.net

### *1.3 Scheme Manager*

The Scheme Manager is Mrs G Donald. She is employed by Maidstone & Tunbridge Wells NHS Trust, and is contracted to the scheme for 0.2WTE for EQA work. The Scheme is charged by Maidstone & Tunbridge Wells NHS Trust for the cost of this work. The Cellular Pathology Head BMS appoints the Scheme Manager. In the event of absence, the Administrator and Organiser will be assigned to Manager tasks.

Contact: Mrs G Donald, Cellular Pathology Dept, Maidstone Hospital, Hermitage Lane, Maidstone, Kent. ME16 9QQ Tel: 01622 224060 E-Mail: gillian.donald@nhs.net

### *1.4 Scheme Administrators*

The Scheme Administrator is Mrs L Knowler. She is employed by Maidstone and Tunbridge Wells NHS Trust and is contracted to the scheme for 0.48 WTE. The Scheme is charged by Maidstone & Tunbridge Wells NHS Trust for the cost of this work. The Scheme Manager appoints the Scheme Administrator(s). In the event of absence of the Administrator(s), the Manager will complete or delegate the administrative tasks.

Contact: South East England General Histopathology EQA Scheme, Cellular Pathology Dept, Maidstone Hospital, Hermitage Lane, Maidstone, Kent. ME16 9QQ Tel: 01622 225738 E-mail: mtw-tr.EQA@nhs.net

### *1.5 Scheme Quality Manager*

The Scheme Quality Manager is Mrs H Dasley. She contracted to the scheme for 0.05 WTE. The Scheme is charged by Maidstone & Tunbridge Wells NHS Trust for the cost of

this work. In the event of the absence of the Quality Manager, the Pathology Quality Manager will deputise. The Quality Manager is appointed by the Head of Pathology.

Contact: Mrs H Dasley, c/o EQA Office, Dept Cellular Pathology, Maidstone Hospital, Hermitage Lane, Maidstone, Kent ME16 9QQ. Tel: 01622 225738 E-mail: helen.dasley@nhs.net

The Scheme is managed by Dr Nipin Bagla in conjunction with the Scheme Management Committee which consists of the Organiser, Manager, Administrator and Quality Manager.

No other staff are employed directly on Scheme work.

### *1.6 Availability*

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. When a participant is away from work for a protracted period (e.g. Sabbatical, sickness or maternity leave), then the EQA Scheme office should be informed so that participation can be suspended.

### *1.7 Repertoire*

The diagnostic categories used are as follows:

(i) Breast
(ii) Endocrine
(iii) GI
(iv) GU
(v) Gynae
(vi) Lymphoreticular
(vii) Respiratory
(viii) Skin
(ix) Miscellaneous

### 1.8 Participation & Coverage

Participation in the South East England General Histopathology EQA Scheme is open to any consultant pathologist or Associate Specialist within the region of South East England (covering London, Sussex, Essex, Surrey and Kent), although applicants outside the area will be considered on a case by case basis. Current coverage includes Histopathologists from South Wales and a small group of GMC-registered Histopathologists currently working overseas.

### 1.9 Enrolment of New Participants

It is the duty of the Head of the participating laboratory to notify the EQA Office of new staff wishing to join the scheme, or of staff leaving the department and the scheme.

When the EQA Office is made aware of a pathologists' desire to join the scheme, the prospective participant is required to complete an eligibility check prior to the application being approved. The scheme will only accept applications from Consultant Histopathologists or Associate specialists who report independently. Long-term locum Consultant pathologists are also able to participate providing they report independently without supervision.

If the prospective participant's eligibility is not accepted, the request is referred to the Scheme Manager and the prospective participant will receive notification within 7 days of the initial application being made.

Returning participants will be re-assigned their previous confidential code, and their original scheme agreement will remain in place.

If the prospective participant is eligible a welcome email pack is sent, which contains a copy of the Participants' Manual (this document).

The prospective participant is asked to read this document, then sign and return the Participant Manual agreement form that he/she wishes to participate on these terms. Results will not be issued unless the EQA office holds this signed agreement.

All participants must confirm whether or not they practice in the UK and provide their GMC number if applicable. All participants are required to inform the EQA Office of any changes.

On receiving this information, the EQA office will enter the new participant's details onto the mailing list, such that the new participant can join the next circulation of EQA material from its start.

New participants will receive an invoice for participation on a pro-rata basis.

The Administrator will issue a confidential code number which is not known to the Organiser or Scheme Quality Manager.

Responsibilities of the EQA Participant

1. To provide an e-mail address for all EQA communications
2. UK participants to provide a postal address of an entity that is legally identifiable and accountable for the purpose of slide circulation and written communication.
3. All International participants to provide a secure email address for all private and confidential communications.
4. To return the Participant Agreement Form to the EQA office.
5. Provide the EQA office with any diagnostic categories for exclusion from scoring (which will be specified on the certificate of Participation).
6. To be ultimately responsible for payment of fees.
7. To ensure that all glass slides that are not viewed in a laboratory environment have suitable storage and security. Slides must be transported, stored, and maintained in stable temperatures (i.e. not kept in a hot car or on a sunny window sill) and safely i.e. out of harm's way of a dog, cat, child etc).
8. To provide cases for use in the Scheme.
9. To inform the EQA office in the event of protracted non-participation due to sabbatical, sickness or maternity leave in order that membership can be suspended or the wish to leave the scheme.

10. To return responses in a timely fashion before the deadline date.
11. To ensure responses are your own and are not the result of collusion with colleagues.
12. To participate in the consultation process
13. To reflect on any result not in consensus with peers and determine any learning or change to practice
14. To share content of certificate of participation with appraiser
15. To Participate in Scheme meetings, or, if unable to, pass any views on Scheme running to the relevant Scheme Advisory Panel member
16. To be aware of the Scheme's quality Policy (e-mailed to all participants).
17. To ensure the authority to provide cases for the scheme is gained from the participant's employer / laboratory provider.
18. To provide GMC number (if registered) and confirm whether practicing in the UK.
19. To inform the EQA Office of any changes to their personal or professional information.

Responsibilities of the Head of Departments

1. To inform prospective participants of the EQA Scheme
2. To inform the EQA office of prospective new participants (including e-mail address)
3. To inform the EQA office of participants leaving the Scheme
4. To ensure the slides are circulated amongst the department's participants and sent onto the next department in a timely manner.
5. To ensure that all paying participants participate in at least 2 out of 3 circulations.

### *1.10 Cost*

The scheme is run on a not-for-profit basis. The cost of running the scheme and its supervision is covered by subscriptions from participants. The subscription covers the salaries of the Organiser (0.5 PA), Manager (0.2WTE), Quality Manager (0.05WTE), Scheme Administrator (0.48WTE), postage and stationery, office equipment, accommodation and Trust support services (e.g. finance), slide scanning, telephone and subscriptions to the bodies responsible for the governance of the Scheme.

Prior to invoices being issued, the EQA office approaches each department requesting a Purchase Order number for subscription fees. Should a Purchase Order number not be received or an invoice not paid, the Scheme reserves the right to withhold the circulation of slides, results or certificates. The process of invoicing commences in April of each year.

The costs are reviewed at the Scheme Management Committee meeting and are available by request from the EQA office. The fee may be changed according to circumstances, with advance notification to the Scheme Advisory Panel and subsequently the participants.

Invoices are generated by Maidstone & Tunbridge Wells NHS Trust. An Account is managed for the scheme by Maidstone & Tunbridge Wells NHS Trust. Subscriptions are paid directly into this account.

### *1.11 Data Protection Statement*

Participant personal details are kept confidentially on computer in the Cellular Pathology Dept, Maidstone Hospital for the purposes of running the scheme. Only the Scheme Manager and Administrator will know your confidential code number. Details about performance will always be released via the confidential code number.

The South East England General Histopathology EQA Scheme is committed to responsible data processing in accordance with the General Data Protection Regulations. For more details please review the Privacy Notice on scheme website for further details.

### *1.12 Participants leaving*

Should a participant wish to leave the scheme, they must give the scheme one circulation's notice. If no other pathologist is taking their place, a credit note can be raised against any remaining subscription fee. If another eligible pathologist is taking their place, the credit can be transferred to the new participant.

# 2 SCHEME OPERATION

## *2.1 Obtaining Case Material*

Cases for circulation in the EQA scheme are provided by the participants. The EQA office records the accreditation status of the submitting laboratory.

The use of archival tissue does not require local Ethical Committee approval or individual patient consent provided:

- No more tissue has been removed from a patient in excess of that required for their ordinary medical care.
- Use of the material for EQA does not compromise routine diagnostic assessment.
- The EQA material is anonymous
- The EQA scheme is a not-for-profit activity

Participants are encouraged to send in potential EQA cases at any time and they are reminded at regular intervals by e-mail and at meetings (recorded in minutes) that cases are always required. However, if not enough cases are received by a suitable number of different participants, an appropriate number of requests are sent via email, to participants selected on the basis of not having contributed case material for the longest period, requesting the provision of one or more cases for the EQA scheme.

Submitted cases should be in the form of at least twelve replicate sets of H&E stained sections. Digital only miscellaneous cases are also accepted and should be in the form of one stained H&E slide. Bizarre cases which would not be representative of the routine workload should be excluded. Post Mortem cases and blocks are not accepted. Slides should be sent in with each case labelled in pencil with the laboratory number (no sticky labels and no patient details). Detailed instructions are provided.

Some individuals are asked to send one case that is slightly more unusual & is therefore of educational value and special interest. An audit trail is in place in order to identify all submitted cases at a later date if necessary.

The email inviting case submissions makes it clear to the participant that all relevant clinical information which was available at the time the original report was dictated should be made available to the EQA participants. It is also made clear that the results of any special investigations such as electron microscopy, immunohistochemistry or special stains, should be made available either as replicate slides, replicate photographs or in the form of a description of the result by the submitting pathologist. If any specialist opinion is sought, this information should also be provided.

Participants are supplied with a case submission form to complete the requested information. These forms must be completed when submitting new cases to the scheme. Only one participant's name can be detailed on the case submission form.

Copies of these forms are available to download from our website:
www.mtw.nhs.uk/gps/pathology/se-england-general-histopathology-eqa-scheme/
Patient identifying data must be removed or redacted from copies of histology reports, if these are submitted with the case submission form. The submitting pathologist is asked to check and confirm on the case submission form that the material submitted is of adequate quality and all submitted slides contain the relevant diagnostic features.

All new case material should be transported in plastic slide carriers, using padded envelopes, labelled to EQA. This avoids any damage to slides whilst in transit. If slides are damaged in transit, we will contact you to submit additional slides.

Once a new case has had all the necessary checks approved, one CPD point will be awarded, noting the date submitted. These points will be awarded in the annual scheme certificate issued in April.

On receipt of the case, it will be assigned an EQA number, and all slides, photographs and associated paperwork will be marked with that number and all other identifying marks removed. The slides and photographs are then stored in the appropriate filing cabinets until used.

The Organiser assesses the suitability of all cases for inclusion in the Scheme. When the circulation is ready to be selected, the Organiser chooses 12 cases (10 test and 2 educational) from the case selection trays. The EQA office will label each case with a case number ready for circulation. If educational cases are not available for selection, then no alternative will be sought and the circulation will not include educational cases. Submitted slides will be retained by the Scheme and will not be returned.

## *2.2 Case Selection*

Ten cases representative of a typical diagnostic workload are circulated. Two cases that are more unusual and are for educational purposes only are also circulated (if available). The educational cases are clearly identified and are not scored or used for personal analysis.

Where possible, one case for each organ system and one randomly chosen case from one of the nine organ systems in rotation (the 10$^{th}$ case) will be selected for each circulation plus two educational cases. Although cases are chosen at random from those available at the time, the Organiser will occasionally use their professional judgment to ensure contributing hospitals and previous circulation cases are considered to avoid using the same contributing hospital repetitively. This is performed in conjunction with the Scheme Manager using methods that does not put the Organiser at any advantage.

## *2.3 Case Circulation*

### 2.3.1 Glass Slides

There are three circulations each year beginning January, May and September. Pathologists are organised into groups in order to make the slide circulation run smoothly.

Prior to the start of the circulation, every participating pathologist receives via e-mail:

- A copy of the circulation list.
- Response forms bearing clinical information together with spaces for diagnoses
- A deadline date by which replies must have been received by the EQA office for inclusion in the analysis

Response forms are available to download from our website:
www.mtw.nhs.uk/gps/pathology/se-england-general-histopathology-eqa-scheme/
One response form for each case is provided. All relevant information is included on this form including the clinical details, type of specimen & macroscopic description. Space for diagnostic opinions and weighted scoring is provided. Participants should treat the material and information provided in the same manner as any routine sample. Please provide a diagnosis, or a list of differential diagnoses, together with an assessment of their certainty of each by provision of scores that add up to 10. (e.g. if 90% sure diagnosis is A and 10% sure Diagnosis is B, then allocate Diagnosis A a score of 9 and Diagnosis B a score of 1). Participants are asked to indicate whether the assessment is based on examination of the glass slide or digital image. This is so that the scheme can periodically audit any bias between the two methods.

A sufficient number of slides are assembled by the EQA office to provide one set for each group of participants and three spare sets.

At the start of the circulation, EQA materials are sent to the first hospital in each group. The date of dispatch of materials is logged by the EQA office.

The sets of cases are sent in the order specified on the circulation list, for a variable period of time in each department, depending on the number of participants in each location. At the end of this time, the slides must be sent to the next department and participants should return their responses on the cases to the EQA office Delay in passing on the slides is the most likely cause for the breakdown of the system. In order to prevent this:

- The Administrator contacts the department on the date when the slides should have been passed on. Participants are asked to immediately dispatch the slides, ***whether or not all pathologists in the department have examined them***. Sometimes arrangements can be made for the slides to be sent back at the end of the circulation if a set becomes available. Alternatively, the cases can be viewed digitally. The links to the digital images are on the response forms.

- The Administrator contacts the department on the date when the slides should have been received, asking them to report any problems.
- *Any department repeatedly causing delays is moved to the end of the circulation list for subsequent distributions*
- All accompanying emails / documentation associated with the circulation includes a deadline date, by which all responses for inclusion in scoring must be received by the EQA office.

Whilst the slides are in your department, you are requested to take care of the material as other participants also need to examine them. Slides should be kept away from direct sunlight; they should not be marked in any way; labels should not be removed and coverslips should not be replaced. If slides show any signs of damage on receipt, (including breakage, fading of the staining or marks on the slides), please inform the EQA office so that replacements can be supplied.

In the event that there are any changes within the circulation, for example any errors in the response forms etc, the scheme will inform the participants in a timely manner to avoid any unnecessary delays or disruptions to the circulation.

### 2.3.2 Digital Images

All slides are available to view electronically via our website: www.mtw.nhs.uk/gps/pathology/se-england-general-histopathology-eqa-scheme/ under the “current round” banner

They are available to all participants either as a primary method for viewing the slides or as a back-up secondary method.

The slides are scanned at x40 magnification. It is the responsibility of the participant to ensure the digital images are viewed on appropriate quality IT equipment.

### 2.3.3 Diagnostic Category Exclusions

The scheme is able to accommodate the exclusion of areas of Histopathology which are not part of a participants' normal practice. These cases are excluded from the personal scores. If there are any areas of pathology (within the confines of the diagnostic categories specified in section 1.7) that a participant does not cover and does not wish to be scored on, the office must be informed in writing, at the time of registration of the participant or prior to the start of the current circulation. Participants cannot be exempt from part of a category (e.g. liver – you must exempt from the GI category)

Please note that participants who re-join the scheme will need to re-apply for any previously held category exemption status, as outlined above.

Please note: it is mandatory for participants to take part in the miscellaneous category. Exemptions will be specified on the Certificate of Participation. Participants are expected to submit their responses for a minimum of 5 out of the 9 diagnostic categories in order to be an eligible participant of the General Histology EQA scheme. (Please see 1.7 for list of diagnostic categories).

**Please note: Exemptions may affect scoring on non-exempted completed categories.** e.g. If you do not achieve full marks for a circulation, exemptions can reduce your overall ranking compared to those with fewer or no exemptions. This effect becomes more pronounced as the number of exemptions increases**.**

## *2.4 Maintaining the Circulation*

At the dates indicated on the circulation list, the EQA Administrator contacts the relevant participants to remind them that they should post the EQA material to the next participant.

At appropriate dates, as indicated by the circulation list, the EQA Administrator also rings or e-mails the relevant participant to ascertain whether or not they have received the EQA slides.

In the event of the EQA office being made aware of a breakdown of the slide circulation system, the EQA scheme Administrator will attempt to trace the missing slides. If necessary, a spare set of EQA material will be sent out by the EQA scheme Administrator to maintain the circulation, if such a set is available.

### *2.5 Receipt and Analysis of EQA Responses*

**Please note that participants must have returned their signed Scheme Agreement form to be able eligible to participate in a round**.

Participants should send their responses to the circulation, bearing their confidential code number, to the EQA scheme office, by e-mail. (Please note: It is the responsibility of participants to submit typed responses for the EQA Scheme. Although, PDF attachments are preferred, but we also accept Word documents. Please do not provide SharePoint links or handwritten responses, as these will be returned as invalid.

Please refrain from including the Scheme Organiser in your email correspondence. Since the Organiser is an active participant in the scheme, we aim to maintain impartiality and avoid any potential bias.

Postal responses are accepted (but not encouraged). On arrival, they are separated from anything that might identify the participant, such as an envelope bearing a post code. Postal responses are date-stamped to record the date of receipt.

Participation records are updated and all responses are collated in numerical order.

Participants who return their responses electronically will receive an e-mail to confirm receipt of the responses by the EQA office. If such an e-mail is not received, it is the responsibility of the participant to request confirmation. If Participants submit their responses by post and a confirmation of receipt is required, they should contact the EQA office.

Participants are required to confirm a statement for response authenticity, to affirm your responses are solely yours and not influenced by discussions with colleagues, double-click in the header area of the response form provided and mark with "x" in the checkbox. Responses lacking this confirmation will not be accepted and returned as invalid.

Participants are not permitted to submit amendments or further responses after their responses have been received within the EQA Office. Participants are only permitted to omit a response to a case if an exclusion from one or more diagnostic categories is already held on file. This request should be received prior to the slide circulation being started, otherwise a response of "not answered" will be entered, attracting a zero score. Participants will be made aware of the deadline date for receipt of responses via emails and on the response forms. Once the deadline date has been reached, no further responses will be accepted without express prior agreement.

All slides must be returned to the EQA office at the end of each circulation for quality checks. Should the slides not be returned in a timely manner, the management reserve the right to review future participation using glass slides.

The Manager enters the participants' diagnoses into the RESPONSE Histopathology EQA database management system, in accordance with the instructions in the user's manual under the authority of the Organiser. (*J. Clin Pathol* 1993:46;357-63). (Back-ups of this database are made daily and kept on the MTW server in the IT department).

If a participant fails to allocate certainty values to the responses, the marks will be equally split between the number of diagnoses present. For example, if a participant sends in two responses to a case and does not mark each response with a confidence score (reflecting their certainty in the differential diagnosis / diagnoses provided that add up to 10) , then the Manager will add a value of 5 to each of the two responses. If there is more than one response the scores will be split and divided between the responses equally. Conversely, if a single diagnosis is provided, the score allocated will be 10.

When a circulation has been completed the RESPONSE application is used to calculate the popularity of each diagnosis proffered on each case.

### *2.6 Case Consultation*

Proposals to merge diagnoses are sought through a consultation process open to all participants. Those that take part in the consultation become the expert participant group.

To ensure the integrity of the expert participant group, merging suggestions made by a participant excluded from an organ system are disregarded.

For the merging suggestions for an individual case to be valid, the expert participant group for each case must consist of at least 50% of the total number of participants for a case.

This case consultation exercise is circulated by e-mail to all participants. Although not mandatory, **participation in this case consultation exercise is strongly encouraged and an additional CPD point is awarded for participation in this exercise**.

Participants are able to participate in the Case Consultation whether or not they have sent in responses for the circulation providing they are not excluded from the diagnostic category.

At this stage, the submitted diagnosis from the original contributor and the popularity scores of each diagnosis are withheld from the expert group to avoid bias in obtaining consensus.

The purpose of consultation within this scheme is to

- Decide if any of the diagnostic categories proffered by the participants overlap unduly and should be merged. The system which generates the personal reports assumes that a participant who has made one diagnosis with complete confidence (score 10) considers all the other diagnoses in the list to be wrong. It is therefore important that each diagnosis in this list is sufficiently broad so that it effectively excludes all the others.
- Decide if any of the cases are inappropriate for the EQA scheme. A case may be considered to be too obscure or specialist, such as a rare neuropathological diagnosis in a general EQA scheme, or it might have been circulated with

inadequate or misleading information. Often these cases will be excluded by statistical analysis after consultation as consensus on merging diagnoses and a qualifying popularity score is not achieved.

Majority decisions will be carried with regards to decisions on individual cases. Consensus modelling is used to determine statistically the merges that should take place. This is clinically validated by the organiser who will take into consideration the participants' comments.

A diagnosis must reach at least 75% consensus from participants in order to use a case for personal scoring. If a case does not meet this criterion, it will be excluded from the circulation and is not used to calculate personal results.

In the unlikely event that cases from 4 or more organ systems are excluded from scoring in a single circulation, the whole circulation will be void and no participant scores will be issued.

Participants are given a time period of 2 weeks in which to complete the consultation exercise and return their comments. The case consultation document is available to download and the slides are available to view electronically via the Scheme website: www.mtw.nhs.uk/gps/pathology/se-england-general-histopathology-eqa-scheme/

## *2.7 Feedback to participants / Results*

When all opinions from the consultation have been returned (by a deadline date), the merge suggestions and comments are collated, statistically analysed and the outcome sent to the Organiser for clinical validation. The majority decisions are carried forward for preparation of the final results. Once the merge decisions have been made, an educational virtual case discussion meeting is held by the Organiser which provides participants the opportunity to understand the reasons behind scoring, merging and/or why cases were excluded. Please note that the meeting is not an opportunity to alter decisions. One CPD point is awarded for attendance to more than 50% of the meeting.

Following the meeting, the Manager makes the amendments to the database as instructed by the Organiser.

Participants will then receive a personal analysis indicating the degree of correlation between their diagnoses and the consensus of the group. This is done by computer and ***does not*** involve "marking" by the Organiser. The data validation systems provided by the RESPONSE application are used, including a visual check to ensure that duplicate entries have not been made.

A histogram giving the distribution of the accumulated "scores" of each participant is also sent, permitting the participant to see in private how his/her performance compares with their peers. The programme which runs this system is described in J. Clin Pathol 1993:**46**;357-63. This scoring system has been approved by the RCPath Interpretive EQA Steering Committee.

After the individual scores have been calculated, the Manager checks the database to test whether any of the participants fulfil the criteria of persistent substandard performance as defined in the substandard performance section and modified from time to time by the RCPath Steering Committee.

In the case of a pathologist making diagnoses which are markedly at variance with the consensus, the feedback system will make that pathologist aware of the position. It would be the responsibility of the individual to take remedial action. Should the majority of participants' diagnosis differ from the original reported diagnosis, the submitting participant will be informed.

**Score calculation:**

For each case, each proposed diagnosis is allocated a popularity score, based on the percentage of participants suggesting that diagnosis during slide circulation. Where differential diagnoses have been proposed, that differential is considered in the calculation. (e.g. if 8 individuals of 10 allocate the same diagnosis a score of 10 and the other two do not allocate any score to that diagnosis, then the popularity score is 0.8).

After the consultation process, the popularity scores of merged diagnoses are summed. The most popular diagnosis (provided at least 75% of the participants agree that diagnosis) is allocated a score of 1. All other diagnoses are allocated a percentage of that score, dependant on the popularity score of the diagnosis.
An individual's score for each case is calculated by multiplying the score for their proposed diagnosis by their confidence level in that diagnosis. Where two or more diagnoses were proposed by a participant, the score for each diagnosis is calculated and added together.

The score for the circulation for a participant is calculated as a percentage total of all the cases for which a participant is not exempt.

The percentage scores are then ranked and those (UK participants) in the bottom 3% identified.

Personal reports are then printed for UK participants, and emailed only to international participants using secure encryption. Only a single personal report is issued and it should be considered as final. It indicates the end of the circulation. If there is ever a need for additional reports to be issued, these will be clearly marked as such.

The UK participants who fall into the lower 3% of responses will have their position highlighted on the second page of their personal report sheet. The reports are sent via the postal system by the EQA office to the appropriate participants. The Manager also sends a cumulative analysis of the participant's results to allow recognition of trends in performance. The release of final reports is made on the authority of the Scheme Manager.

Participants are free to utilise their personal results in any way they wish and should include them as part of their CPD evidence at appraisal. The confidentiality of the personal results is the responsibility of the participant. Personal results may be printed and discussed within the Scheme staff if necessary for the purpose of quality management, but will remain anonymous except to the Manager and Administrator.

**Please note, participants who have not returned a signed scheme agreement form, or who have not paid their subscriptions within 6 months of invoice issue, will not receive personalised results nor a certificate of participation.**

Participation certificates are created and distributed via email annually in the spring, relating to participation in the previous calendar year. The certificates will show CPD points for the number of rounds and consultations participated in, any excluded diagnostic categories, the number of new cases submitted, and attendance to the EQA Case Discussion meeting.

If a participant has any queries regarding any aspect of the circulation, they have until 4 weeks after the closure of the circulation (the date the results are circulated) in which to contact the EQA office. This should be done via email to avoid any delays and ensure a timely response.

### *2.8 CPD point allocation*

Submission of responses to the general cases: 2 CPD points.
Submission of responses to both educational cases: 1 CPD point.
Participation in the case consultation: 1 CPD point.
Submission of new cases: 1 CPD point per case.
Case Discussion meeting: 1 CPD point

## 3 SUBSTANDARD PERFORMANCE

After the calculation of personal scores for each circulation, the RESPONSE database places the individual participant scores for that circulation in rank order. A defined percentage at the bottom of the listing is identified. In accordance with current RCPath recommendations the percentage is set at 3%. Rankings in the bottom 3% constitute substandard performance.

All UK practising participants will be subject to poor performance monitoring and will be reported to the NQAAP (National Quality Assurance Advisory Panel in Cellular Pathology) in the event of triggering a second action point.

Participants that do NOT practise in the UK will NOT be subject to poor performance monitoring or reported to the NQAAP and will be excluded from the ranking if falling in the bottom 3%.

The Manager checks whether any participant whose score falls within this range has also had a score fall within this range in the preceding two circulations that they have participated in. If such a participant is found, this constitutes the first action point.

Any participant who resigns after triggering an action point and then enquires to re-join the scheme after 12 months, will need to provide evidence to Organiser that corrective actions have been taken. The Organiser will review the evidence submitted and decide if they can re-join the Scheme.

If a participant re-joins within 3 years of resigning after triggering an action point, they will be subject to surveillance monitoring for 3 rounds and could be subject to triggering a 2nd action point.

### *3.1 Definition of Sub-Standard Performance & Action Points*

These recommendations were originally developed by the Working Group on Histopathology Quality Assessment Scheme Accreditation, from the discussion document "Standard operating procedures for Histopathology External Quality Assessment Schemes" published in the *Bulletin of the Royal College of Pathologists*[=], and subsequently amended after consultations carried out by the Royal College of Pathologists and the Department of Health. They were further developed in 2017 (Principles and Guidance for Interpretive External Quality Assessment Scheme in Laboratory Medicine (G153)). These procedures only apply to UK-practicing participants.

### *3.2 Definition of the First Action Point and Remedial Action*

After each circulation has been "scored", the scores are ranked[1] and the participant code numbers of those ranked in the bottom 3% are identified. Any pathologist can make

[=] **Furness PN. Standard Operating Procedures for Histopathology External Quality Assessment Schemes. *Bulletin of the Royal College of Pathologists* 1995;**92**:22-5.**

[1] All participants with the same score will be ranked the same, thus all participants scoring the same highest total score for all cases that they participate in will be ranked 1. Of 100 participants, if 99 participants achieve the same maximum score, they will all be ranked 1 and the 100th person will be ranked

occasional erroneous diagnoses or be adrift from the consensus without being clinically significant, so the first action point should therefore be defined as: ***A 1st Action Point is reached when participants' results fall in the lower 3% in two out of three consecutive circulations in which that individual participates.***

The Organiser sends a "Dear Colleague" letter to that participant, pointing out the position, offering appropriate sources of advice and assistance and informing the participant that if they trigger a second action point, the Chair of NQAAP will be asked to investigate. The letter will indicate that the participant should discuss their interpretive EQA status during appraisal and agree remedial steps as appropriate. Alternatively, the participant may decide to withdraw from the area of service covered by those cases which contributed to the overall scores and adjust their scope of work accordingly. It is also made clear, that for the next three circulations, a failure to participate (subject to availability), will be considered equivalent to a zero score. The letter is sent by "signed for" post.

The participant is asked to confirm that this letter has been received, by reply through the EQA office bearing no identifying marks other than the participant's code number. The reply should confirm that this issue will be discussed during appraisal and specifically addressed in their PDP, or that the participant has ceased to deliver a service in the areas covered where drop in scores contributed to the overall score as relevant.

If there is adjustment to working practice and participation in the EQA scheme, the participant should state this adjustment to the Scheme Organiser, formally withdraw from the Scheme / diagnostic categories (if appropriate) and inform their local management. Please note that should the participant withdraw from the scheme at this point, a certificate of participation will not be issued.

If such a reply is not received within four weeks, a reminder letter is sent; if a reply is not received within another four weeks, an email reminder is sent to the participant on the

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100. This 100th person will be identified as falling in the bottom 3% ranking. Thus, the ranking does not depend on the absolute score but score compared to other participants.

deadline date, if no response from the participant, the Organiser informs the NQAAP Chair of the position.

***Prior to referral, the Manager and Quality Manager will review the statistical impact on scores and ranking due to exemptions.***

This letter is identified by the participant's number only and the event of a first action point is recorded in EQA records.

### *3.3 Definition of the Second Action Point and Subsequent Actions*

If the participant again falls within the bottom 3% (or does not participate) **in any of the next three circulations,** this is considered to be triggering the second action point.

The Organiser informs the Chair of NQAAP, who will initiate an appropriate investigation. The panel chair will be informed of the identity of the Participant. The investigation will place emphasis on tracing problems and implementing remedial measures rather than punitive action. If the problem cannot be resolved or if it is considered that patients are at risk, it would then be necessary for NQAAP to inform the doctor's responsible officer.

The Chair of NQAAP is entitled to be informed of the identity of the relevant participant by the EQA Manager upon request. At no time should the Scheme Organiser be informed of the identity of any participant under such investigation.

If the participant being investigated by NQAAP is a member of the Scheme Advisory Panel then that member will be suspended from their role until that investigation is complete. Confidentiality will be maintained as only the Manager/Administrator needs to / will know of the temporary suspension.

Should the participant being investigated be the Organiser, they will also be suspended from their role and the Manager will approach a member of the Scheme Advisory Panel to deputise in the Organiser's absence. It is inevitable that in these circumstances,

confidentiality will be compromised, but this is accepted by the Organiser when participating in the Scheme.

Nothing in this document detracts from the GMC requirement that any doctor should take appropriate action to protect patients if a colleague's performance appears to put patient care at risk. Consequently, if the Organiser becomes convinced that action is needed, there is an obligation not to delay. However, if doubt remains in the Organiser's mind as to whether rapid action is necessary, it will probably be prudent to put the data in anonymous form to the members of the SAP and NQAAP and ask advice on the most suitable course of action.

Prior to referral, the Manager and Quality Manager will review the statistical impact on scores and ranking due to exemptions.

The presence or absence of a plausible reason for the sub-standard performance should not affect this procedure.

These procedures would only be activated in exceptional circumstances, and should cause no more concern to EQA participants than the current possibility of being reported for incompetence by a colleague. The main purpose of this Histopathology EQA scheme remains educational, and it is anticipated that it will continue to be valued by pathologists for this reason.

ISO 15189:2012 (competence of medical laboratories) requires laboratories to participate in inter-laboratory comparison programmes (e.g. EQA schemes) that substantially fulfil the requirements of ISO 17043:2010. The South East England General Histopathology scheme is ISO 17043:2010 accredited. By participating in this scheme, the ISO 15189:2012 standard clause 5.6.3.1 will be met.

### *3.4 Confidentiality*

Each participant is given a code number ***known only to themselves and the Scheme office staff (Manager and Administrators).*** This code must be entered on the returns

to allow a personal statistical analysis of the results. ***It is the responsibility of the Organiser to ensure that the identity of participants is known only to the EQA Office staff and that strict confidentiality will be maintained.***

The EQA scheme Organiser is not aware of the identity of the author of any diagnosis other than his/her own.

This is achieved by a confidential numeric code system generated by the EQA Manager or Administrators. The EQA office has a list of EQA scheme participants in electronic form which is password protected. Against each name the Manager or Administrator enters a numeric code. This file represents the only link between the codes and the participant names. It is not made available to the Scheme Organiser.

The Scheme Organiser therefore communicates to participants when identified by their code number only through the scheme Manager or Administrator.

The link between participant names and code numbers may be divulged by the EQA scheme Manager/Administrator only under three circumstances.

(i) In writing by post to a participant who requests a reminder of his/her code number. Code numbers must not be divulged by telephone or e-mail.

(ii) UK practising participants only will be subject to confidentiality breaks to NQAAP by the Scheme writing to the Chair of NQAAP, but only when justified by procedure in 'Substandard Performance' section, in order to investigate appropriately a case of persistent substandard performance in the EQA scheme.

(iii) In the event of a serious complaint in order for the Clinical Director of Maidstone & Tunbridge Wells NHS Trust to investigate.

In the event of point (i) and (ii) the participant will be sent a letter informing them that their confidentiality will be broken. No EQA result or details of a participant's individual performance either within a circulation or over a period of time may be divulged to any other authority.

### *3.5 Non-Participation*

The minimum acceptable level of participation in the EQA Scheme is two out of three consecutive circulations of the scheme within the financial year, *providing the first action point has not been reached.*

Non-participation in an EQA circulation for reasons of illness, prolonged annual or sabbatical leave or maternity leave is acceptable and should not equate to sub-standard performance. It is the responsibility of the participant to notify the EQA office of non-participation due to any of the reasons above, so that the participant's record can be correctly amended. Non-participation due to a heavy routine workload is not an acceptable reason.

Any participant funded by their department, who does not participate in at least 2 out of 3 consecutive circulations within the financial year will be emailed to ask if they still wish to remain a member of the scheme. If there is no response within 4 weeks, a second email should be sent. If there is no response within a further 4 weeks of the second letter being sent, their Head of Department will be informed.

If they indicate that they do wish to remain in the scheme, but still do not participate in the following round, their Head of Department will be informed of their non-participation. Should there be no response from the Head of Department after 4 weeks, a letter will be sent to the Medical Director of that Trust.

Participation is voluntary, although if participation is being funded by a public body, there is a moral obligation to participate. A certificate of participation ***will only be issued to pathologists who provide responses to at least two of the three most recent circulations.*** *Furthermore, if a participant chooses to resign after triggering a 1st Action Point, a certificate of participation will not be issued.*

Non-participation in any of the three subsequent circulations after the first action point has been triggered, automatically counts as substandard performance and will result in a referral to NQAAP for investigation.

### 3.6 Communications

Communication between the Scheme and its participants, regarding all matters, is mainly performed using e-mail and attachment of documents.

There are two exceptions to this:

1. The participant's confidential code can only be sent in writing by post.
2. Personalised results after a circulation will be sent by post to UK participants (and by secure email to international participants).

For this reason, a participant cannot be registered without an e-mail address. By payment of subscription of the fees for participating in this scheme, you give permission for the use and storage of your email account address for the purpose of notification of scheme activities.

All written communications from participants to the Organiser or the EQA office will be stored in a file for a minimum of four years.

Where a comment is made, the Organiser or EQA office receiving the communication will make a written note summarising the communication which will be dated and stored.

The Scheme aims to resolve all queries within 20 working days.

### 3.7 Complaints

Any complaints regarding the organisation/running of the scheme should be addressed to the EQA Office in the first instance, who will anonymise your query by removing all identifiable information. Please see link for complaint flowchart:

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

The Scheme aims to resolve all complaints within 20 working days.

### 3.8 Annual General Meeting

The Scheme has an Annual General Meeting in early summer of each year, this is a virtual meeting held on Microsoft Teams, to which all participants are invited and encouraged to attend.

Invites are sent out by e-mail in advance and ideas are sought for agenda items. The agenda will include an Annual report, review of Costs & Accounts, user survey results, RCPath updates, future changes to the Scheme etc.

### *3.9 Participant surveys*

Short, targeted user surveys will be conducted throughout the year by means of Survey Monkey questionnaires devised by the EQA Scheme Management team.

Survey responses will be reviewed by the Scheme Management Committee and changes to the Scheme recommended and implemented if considered an improvement to the scheme operation.

Surveys and their outcomes will be presented at the following AGM

## 4 SCHEME MANAGEMENT

### *4.1 Local Governance – Scheme Management Committee*

The scheme is managed by the Scheme Management Committee (SMC). This committee is made up of the Scheme Organiser, Manager, Administrator and Quality Manager.
Their Terms of Reference are available upon request.

### *4.2 Local Governance – Scheme Advisory Panel*

This panel has members nominated from the participants from each region represented in the scheme and overseas members if appropriate. They normally serve for a period of 3 years, but this is renewable. Details of current panel members is available on the EQA website under tab [Scheme Advisory Panel]. Their Terms of Reference are available upon request.

If there becomes a vacancy within the Scheme Advisory Panel, an email will be sent to all participants within the sub-region, requesting self-nominations for the appointment. In the event that more than one participant putting themselves forward, it will be taken to

the Scheme Management Committee for decision. A Chair for the Scheme Advisory Panel meetings will be elected by the members of the panel.

### *4.3 Local Governance – Annual General Meeting*

Comments on the mode of operation of the scheme are invited at the annual AGM. Changes proposed at such meetings will normally be reviewed by the SMC, as below, unless the need is urgent. Suggestions for a change of the Scheme Organiser should be discussed first at this meeting; such suggestions must be considered if made by any scheme member. As far as possible, decisions at the AGM should be made on a democratic basis of those in attendance.

### *4.4 National Governance*

A structured annual report is provided to RCPath Cellular Pathology National Quality Assurance Advisory Panel (NQAAP) on the work of the Scheme, with particular emphasis on any changes in how the scheme runs, actual or planned. Specifically, any changes in these SOPs must be communicated to the SAP and RCPath for approval.

The annual report provided to the RCPath includes any changes in the assessment procedure and in procedures for managing sub-standard performance, and also the number of participants who triggered action in response to sub-standard performance in the previous year.

### *Organisers meeting*

The Organiser and Manager attend an annual national meeting of Organisers responsible for interpretive Histopathology EQA schemes.

### *Managerial accountability*

The Scheme operates from within the laboratories of the Cellular Pathology Department, Maidstone & Tunbridge Wells NHS Trust, with the approval of the Head of Department, and the Trust Chief Executive.

### 4.5 Training

The EQA Scheme Manager, Scheme Administrator & Quality Manager are involved in a training programme as part of their employment in Maidstone & Tunbridge Wells NHS Trust. All scheme staff undergo a training and competency programme.

### 4.6 Slides for Teaching & Training

Glass slides from previous circulations are currently kept in the Cellular Pathology Department at Maidstone Hospital in order for trainee Histopathologists to use them to aid their studies. Please contact the EQA scheme to arrange access. Digital images from 2014 onwards are available via the EQA website.

### 4.7 Maintenance of Procedures

This document, together with the Quality Manual, Quality Policy and administrative procedures document are reviewed annually at the Annual Management Review.

If it is necessary to amend a procedure, or to create a new one, this is conducted by the Manager/Administrator on QPulse; the draft version with tracked changes is submitted to the Scheme Manager or SMC as appropriate for approval. Once approved, the documents are distributed as appropriate. The Participant Manual, Quality Policy and Quality Manual are distributed in PDF format to NQAAP for Cellular Pathology for ratification (6 monthly meetings). These documents are published on the EQA scheme website, along with all relevant EQA information.

When a new version of the participant manual is published and circulated to participants, the scheme assumes implicit consent for the new version.

Should there be an urgent amendment required to a document, the change will be emailed to the participants / members of staff for information purposes, attaching the current document and clearly explaining the amendment.

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