

**External Quality Assessment Scheme
for Gynaecological Cytopathology**

Version 3

**EXTERNAL QUALITY ASSESSMENT SCHEME FOR
GYNAECOLOGICAL CYTOPATHOLOGY**

Protocol and Standard Operating Procedures

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This updated and amended version reflects the evolution of the External Quality Assessment Scheme for Gynaecological Cytopathology and the many comments and issues raised during the operation of the scheme since its introduction in the English Cervical Screening Programme. In particular, we would like to acknowledge the input from the National Laboratory Quality Assurance (QA) Group, members of the EQA subcommittee of the National Laboratory QA Group and the regional facilitators for their efforts in making this scheme a success.

PROTOCOL

1. INTRODUCTION

External quality assessment (EQA) is an essential part of the wider quality assurance function. The fundamental purpose of EQA is to maintain and improve the quality of patient care by promoting a high standard of performance. This is facilitated through an independent system of checking laboratory results by an external agency. Consequently, an acceptable degree of reliability and consistency is achieved through education, advice and support to all participants.

EQA, or proficiency testing, as it has been known, was first introduced into the NHS Cervical Screening Programme (NHSCSP) when the Department of Health Advisory Committee on the Assurance of Laboratory Standards published the *Protocol for a Proficiency Test Scheme in Gynaecological Cytopathology*¹ in 1988. Regional schemes subsequently developed and, although the principles of these schemes were similar, each region developed its own interpretation and methodology.

A national EQA scheme was first introduced in 2003 based on *Recommendations for the Development of Histopathology/Cytopathology External Quality Assessment Schemes*,² which was developed by the Working Group on Histopathology External Quality Assessment Scheme Accreditation in 1998. The recommendations of the Working Group were endorsed by the Royal College of Pathologists. The protocol also drew, where appropriate, from the successful experience of the EQA scheme in breast screening pathology in use in the NHS Breast Screening Programme.

The EQA scheme, in its original version, as outlined in the first version of this publication, was adopted nationally for the 2004/05 round. Subsequent versions of this publication reflect the amendments that have been made to the scheme following feedback from regional Quality Assurance Reference Centres and participants. This protocol and standard operating procedures should be read in conjunction with the *Standards for EQA Schemes in Laboratory Medicine*.³ References to the standards are indicated as (EQA ...).

2. GENERAL DESCRIPTION OF THE EQA SCHEME

The name of the scheme is the NHS Cervical Screening Programme External Quality Assessment Scheme for Gynaecological Cytopathology.

3. SCOPE OF THE SCHEME (EQA A1.1)

The standard operating procedures (SOPs) apply to the NHS Cervical Screening Programme in England.

4. OBJECTIVES OF THE SCHEME (EQA A2.1, E1, H1 and H2)

The objectives of the scheme reflect the needs of the participants. The objectives are to:

- provide an external assessment of the quality of reporting of cervical cytology samples
- maintain and improve quality by achieving consistent good practice
- promote education and training through formal feedback
- identify substandard performance and the reasons for this to enable remedial action
- respond to participant satisfaction and complaints
- achieve recognition through the appropriate accreditation bodies.

5. JOINT WORKING GROUP FOR QUALITY ASSURANCE (EQA A1, A11 and E2)

The Joint Working Group for Quality Assurance⁴ (JWG) is recognised by the Department of Health (DH) as the independent body responsible for pathology EQA in the United Kingdom (Figure 1). Members of the JWG comprise representatives of the pathology professions and societies, chairpersons of the National Quality Assurance Advisory Panels (NQAAPs) and observers from national government offices and Clinical Pathology Accreditation (UK) Ltd (CPA). Its remit is to oversee all EQA in the UK, to approve and register schemes, to set policies and to

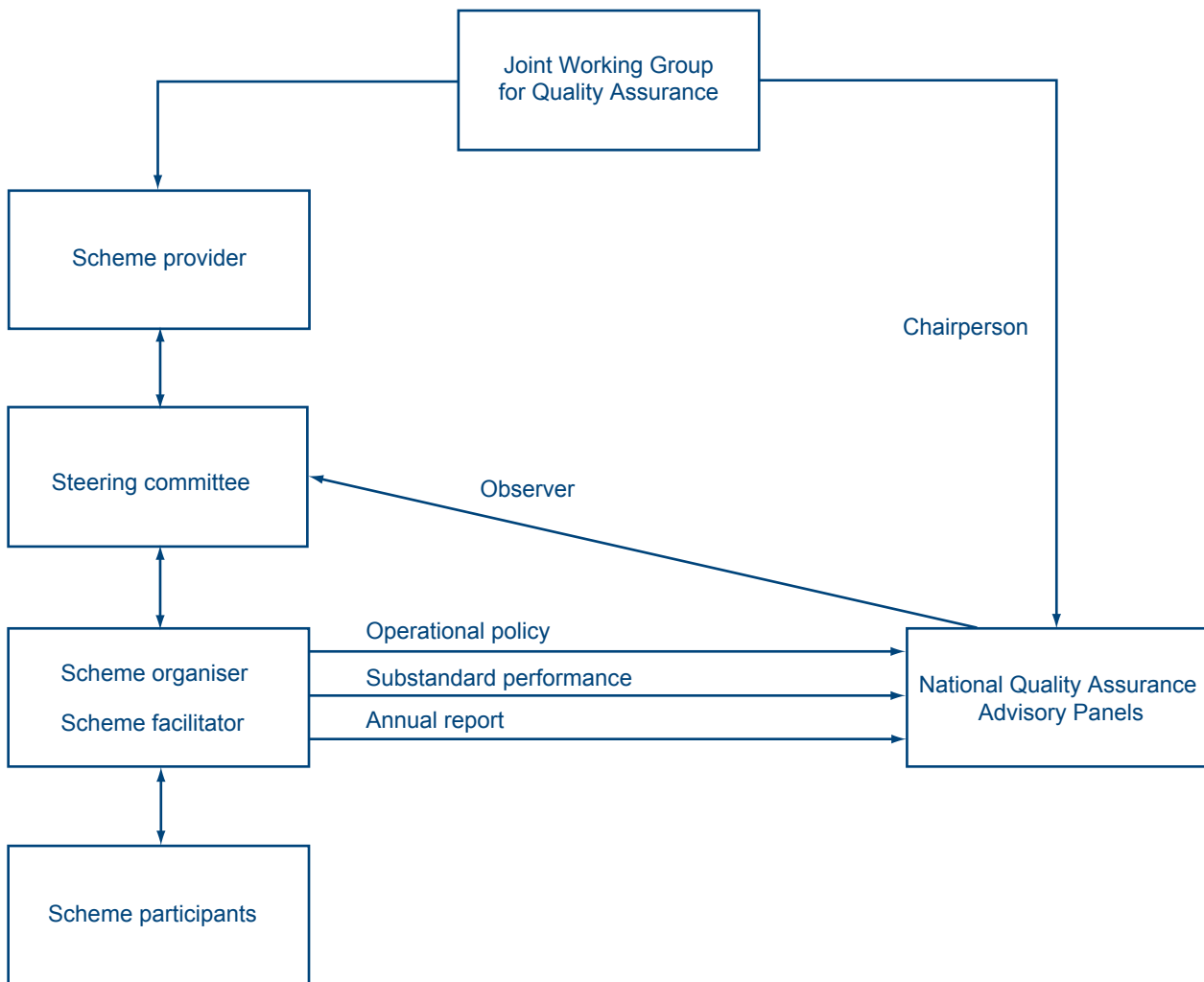


Figure 1 Pathology EQA in the UK.

maintain appropriate professional standards. The JWG is responsible for the recognition of the NQAAPs and steering committees and for scheme-related professional matters. Advisory panels are convened for all pathology disciplines and their remit is to monitor substandard performance.

6. EQA SCHEME ORGANISATION (EQAA1, A3, A4, A5, A7, B1.1, B2, B8, E2, H1, H2, H3, H4 and H5)

6.1 NHS Cervical Screening Programme (scheme provider)

The national office of the NHS Cervical Screening Programme (NHSCSP) is at:

NHS Cancer Screening Programmes
Fulwood House
Old Fulwood Road
Sheffield
S10 3TH
Tel: (0114) 271 1060
Fax: (0114) 271 1089
www.cancerscreening.nhs.uk

6.2 National scheme organiser

The organiser of the scheme at a national level shall be the chairman of the English national coordinating group for laboratory quality assurance (QA), who will be a participant in the scheme.

6.3 EQA scheme steering committee

The steering committee for the scheme is the national coordinating group for laboratory QA. The steering committee is responsible for setting, reviewing and revising the objectives (needs of the participants) of the scheme and includes the chairs of the regional EQA scheme organising committees (see section 6.8). A subgroup of the steering committee, termed the EQA subcommittee, assists and supports the wider group in managing general scheme activity and the annual review.

6.4 Scheme secretary

The secretariat for the national scheme is provided by the national office of the NHSCSP.

6.5 National quality manager

The national quality manager is provided by the national office of the NHSCSP. This individual ensures that the quality management system for the scheme functions correctly. The national quality manager is responsible to the scheme organiser and shall not be the scheme organiser him- or herself.

6.6 Operation of the scheme

Owing to the nature of cervical cytology, in that it does not have the facility to produce multiple specimens sufficient for all the participants in the scheme, the scheme is operated locally on a regional basis. The scheme is organised through the regional quality assurance framework of the NHSCSP (Figure 2) and the *Handbook for Facilitators*⁵ has been developed to ensure national uniformity in the delivery of the scheme.

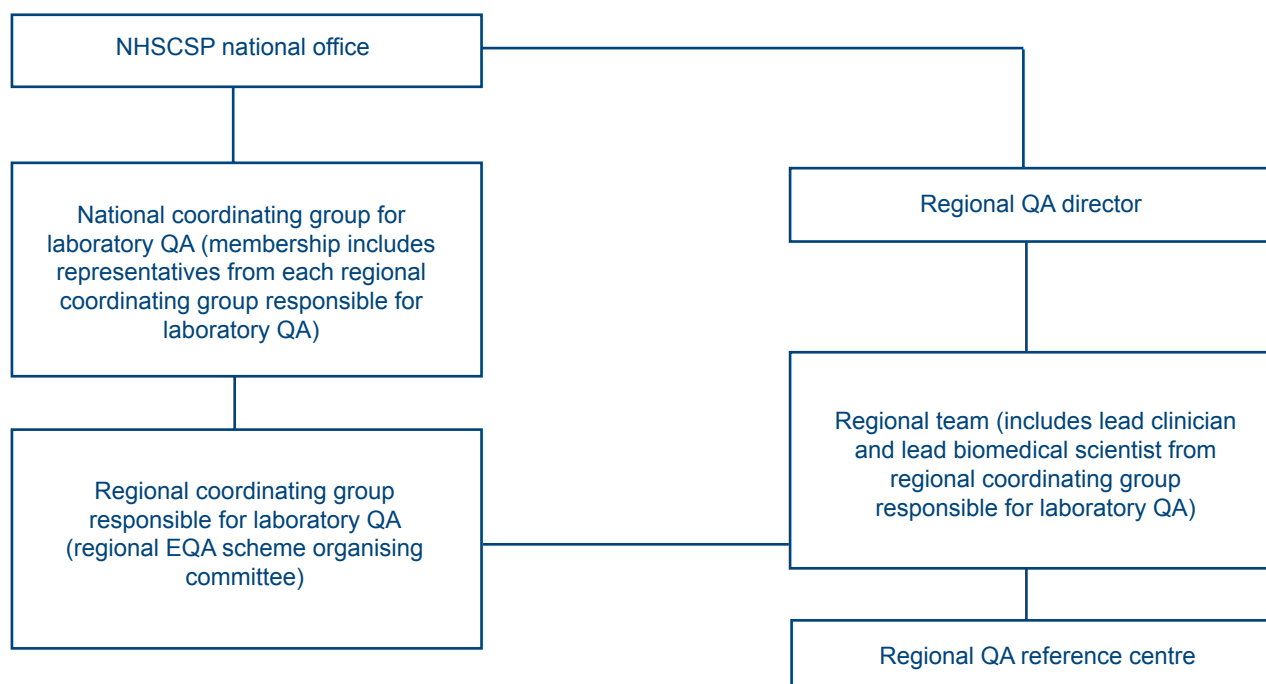


Figure 2 Quality assurance relationships for pathology in the NHSCSP.

6.7 Regional organiser

At a regional level, overall professional responsibility for the EQA scheme is held by one individual (the regional organiser). This individual will be a participant in the scheme. It is recommended that this individual is the chairman of the regional coordinating group responsible for laboratory QA.

6.8 Regional EQA scheme organising committee

The regional coordinating group responsible for laboratory QA will act as the regional organising committee for the EQA scheme.

6.9 Regional EQA facilitator

A regional EQA facilitator undertakes the day-to-day running of the scheme at a regional level and acts as the regional EQA scheme secretary. The facilitator will be based at the regional quality assurance reference centre (QARC). The duties of the facilitator will include organisation of slide sets, delivery and collection of slide sets, analysis and notification of results. An essential part of the post will be to maintain the confidentiality of participants in the scheme, whilst allowing anonymous linkage between involved parties in the event of persistent substandard performance. Only the facilitator, who is not a participant in the local scheme, will know the identities and scores of the local participants and will not divulge them except under the terms of this protocol. The facilitator will be responsible to the regional organiser for the efficient running of the scheme and, for other functions, to the regional QA director who employs him or her.

All regional EQA facilitators in England meet on at least an annual basis to discuss the scheme.

6.10 Regional quality manager

The regional quality manager ensures that the quality management system is effective at a local level and is not the regional organiser.

6.11 Relationships within the scheme

Relationships within the EQA scheme are shown in Figure 3.

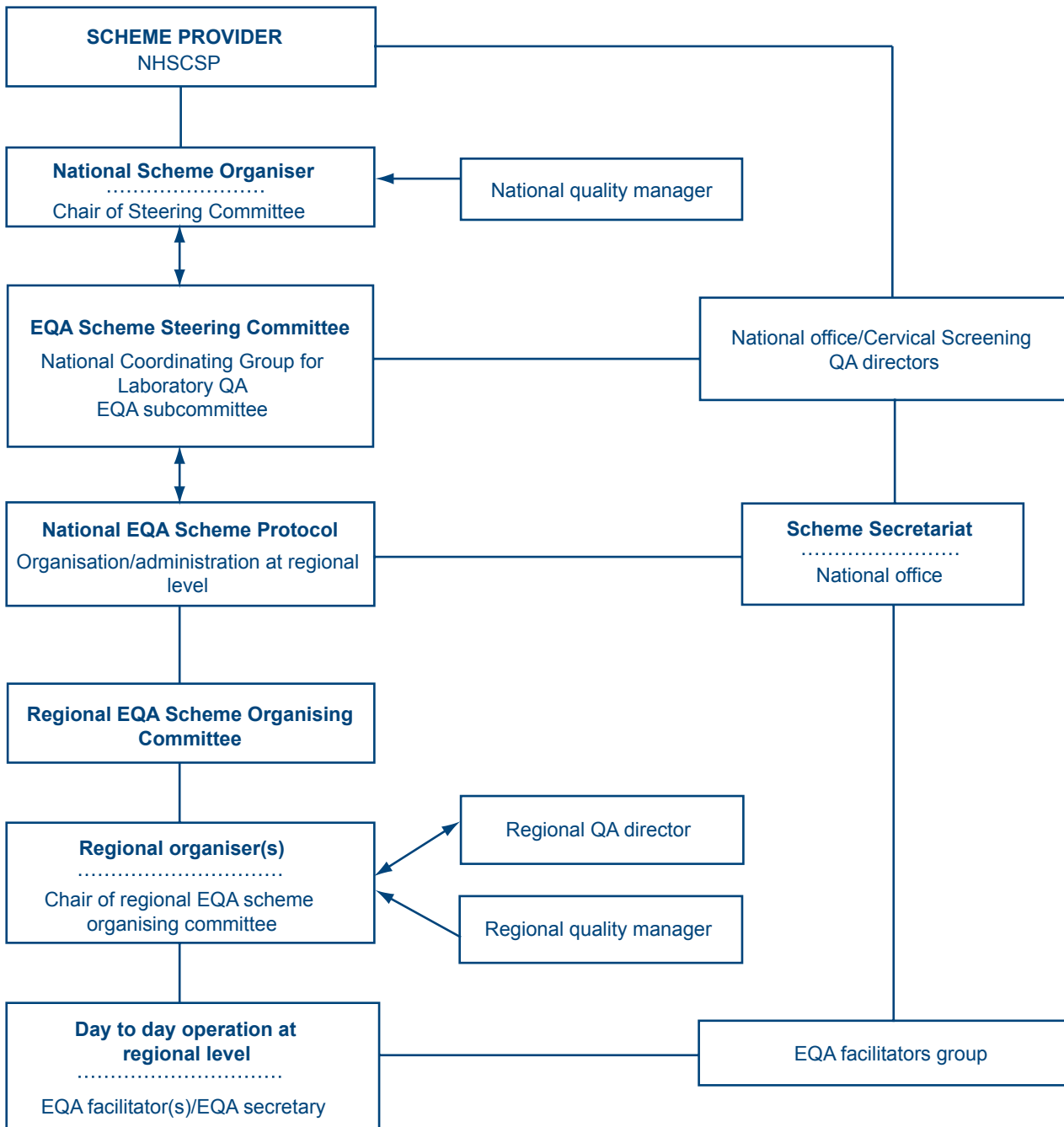


Figure 3 Relationships within the EQA scheme.

- 7. PARTICIPATION (EQA A1.4b, E3 and G1)**
- Participation is mandatory for all individuals (including staff working as locums) reporting gynaecological cytology for the NHSCSP. Names, addresses and participant code numbers will be recorded by the regional facilitator in the participant files, which will be held securely at the regional QARC.
- Guidance for the NHS published in EL(98)2, *Oversight of Provision of External Quality Assessment Schemes in Histopathology, Cytopathology, Cytogenetics and Molecular Genetics for Pathology Laboratories*, makes participation in EQA schemes mandatory for those providing the NHS Breast and Cervical Screening Programmes.⁶ It also requires all cervical screening laboratories participating in the NHSCSP to apply for accreditation by Clinical Pathology Accreditation (UK) Ltd (CPA). Participation in relevant EQA schemes is a prerequisite for CPA accreditation.⁷
- 8. CIRCULATION OF CASES (EQA D3, E3, E4.2 and G1)**
- There are 10 slides in each slide set per circulation and further slides may be included for special educational interest.
 - There will be two rounds of EQA (circulation of slide sets) in each EQA year (April to March) from April 2008.
 - Slides will be circulated to all laboratories participating in the NHSCSP. A full list of these is available at the national office and each QARC holds a list of the laboratories for which it is responsible.
- 9. SELECTION OF CASES**
- The slides will be good examples (not necessarily easy), and may include all classifications recognised by the British Society for Clinical Cytology (BSCC), that is negative, inadequate, borderline change, grades of dyskaryosis, ?invasive squamous carcinoma and ?glandular neoplasia. These classifications are further explained in *Achievable Standards, Benchmarks for Reporting and Criteria for Evaluating Cervical Cytopathology*.⁸ Cases involving infections may also be included in EQA.
- The final composition of slide sets for circulation will be devised by the local facilitator according to guidance published in the *EQA Scheme for Gynaecological Cytopathology Handbook for Facilitators*.⁵ Circulated cases will be typical of routine practice and not rarities, although, by necessity, slide sets will include a higher proportion of abnormal cases than seen routinely.
- Adequate clinical information will be provided by the submitting laboratory for each slide, derived from the standard request form (currently the 2003 HMR 101/5 or its local equivalent).
 - All NHSCSP laboratories which are currently performing satisfactorily (not at a national action point) according to the *External Quality Assessment Scheme for the Evaluation of Papanicolaou Staining in Cervical Cytology*⁹ will be required to submit slides to the QARC with a consensus opinion from at least a primary screener, checker and cytopathologist/advanced biomedical scientist practitioner (ABMSP). Laboratories acting as 'spoke' laboratories for liquidbased cytology (LBC) processing arrangements will also be eligible to

submit slides if their 'hub' laboratory meets the above requirement. Duplicate slides produced from a single LBC sample can be submitted by a laboratory, but they should be considered as entirely separate cases for EQA purposes, since it cannot be assumed that they will have identical consensus.

Histology is obtained routinely only in the case of samples which show a high grade (moderate dyskaryosis or worse) abnormality. It is therefore not possible for every category of report used in cervical cytology to have histological confirmation. However, histological confirmation of the diagnosis is required for any high grade abnormality which is to be included. Samples showing mild dyskaryosis must have been followed by a subsequent sample or a histological diagnosis which is consistent with the original report on the submitted slide. Borderline slides can legitimately be followed by a negative, low grade or high grade sample and therefore any category of cytology except inadequate will be acceptable following this category. Negative slides will not require recourse to a second negative slide. Inadequate slides must have been followed by a negative sample.

- c A small panel of three participants (including a pathologist/ABMSP, a checker and a screener) will ensure that the submitted slides are technically adequate by individually reviewing the submitted slides. Slides should be assessed for technical quality, consideration being given to items such as stain quality, mounting and cracks.
- d The panel will also reach an agreed opinion, blind to the submitted diagnosis, on classification which is consistent with patient history or histology before a slide can be accepted into the scheme.
- e The panel members should be drawn from a single region, and must not participate in the scheme for which they are reviewing slides. If participating in another region, panel members must agree for their performance in EQA to be fed back to the local facilitator who will manage any issues.
- f The name of the patient and of the submitting laboratory should be obscured for the purposes of the round. However, the identification should not be effaced from the slide. The submitting laboratory will be responsible for concealing the patient details on the slide prior to submission, whilst the facilitator will relabel the slides on receipt to ensure that the details of the submitting laboratory are not visible during panel review and the round. The facilitator will be expected to know the location of every slide in case a patient's slide needs to be found while the slide is included in the circulation. Once the slide is no longer needed for EQA purposes, it should be returned to its submitting laboratory at the end of the round(s). The positioning of previous dots should be recorded by the submitting laboratory for medicolegal reasons and the facilitator should ensure that they have

been removed from the slide before reaching each laboratory in the circulation.

- g The educational value of the scheme may be enhanced by the addition of extra cases to add interest. These should be clearly identified as such and should not be used for personal performance analysis.

10. OPERATION OF THE SCHEME (EQA F2.3 and G1)

10.1 Conditions for examining EQA slides

Participants will be allowed to examine EQA slides under the same conditions as used in their routine practice (ie not examination conditions). However, discussion between participants in the laboratory about the EQA slides must not take place until all participants have seen the slides and recorded their results. Senior members of staff should remind participants of this on each occasion that EQA slides are to be reported, and that any evaluation of personal performance is meaningless if discussion occurs. Discussion reduces the value of EQA and may also propagate false responses, which adversely affect individual performance results. Once all in the laboratory have seen the slides and submitted their responses, discussion is encouraged before the slides leave the laboratory.

10.2 Routine practice and marking of slides

All participants should examine cases in a manner appropriate to their routine practice. Laboratories using different LBC systems will form separate assessment groups for the purposes of EQA. In laboratories where staff routinely use more than one LBC system, participation will be required in only one system, which should alternate between the two systems employed at each round. All participants will receive feedback on all areas and not merely those used for performance monitoring.

10.2.1 Non-medical staff

In NHSCSP laboratories, there are two clearly identifiable tiers of activity undertaken by non-medical staff: primary screening and checking. Currently, staff who are not medically qualified should not be reporting abnormal slides (with the exception of ABMSPs), but should sort slides into those which they will report themselves as negative or inadequate and those which they will pass on to more senior staff as requiring further review. Non-medical staff are therefore to be assessed on this basis. However, many laboratories routinely encourage their non-medical staff to suggest a classification, and this is often a requirement of checkers. The scoring scheme described in section 11 is therefore expected to extend to all staff to enhance the educational benefit of the scheme.

Primary screening

Those individuals undertaking primary screening (usually cytoscreeners and biomedical scientists) decide whether a slide is negative, inadequate or potentially abnormal necessitating referral for reporting. Individuals undertaking primary screening as routine practice should undertake EQA with unscreened and unmarked slides. Pathologists or ABMSPs may wish to participate in this type of EQA in addition to their regular EQA. However, they will not be assessed on this and their responses will not

be included in any consensus calculation or performance analysis for this slide set.

Checking

Those individuals who are experienced cytoscreeners or biomedical scientists have variable duties. As checkers usually undertake some primary screening, they should participate as primary screeners. However, there may be some in this group who do not undertake primary screening at all and normally always receive marked slides. If this is the case, then they should do so when they participate in the EQA scheme, these marks having been placed on the slides by primary screeners when themselves participating in the scheme.

10.2.2 Advanced biomedical scientist practitioner (ABMSP) in cervical cytology

The duties of ABMSPs include signing out of abnormal slides and giving management recommendations. They may, in addition, undertake checking duties and report unchecked slides, thus effectively acting as their own 'checker'. EQA for such staff should be based on slides that have been screened by primary screeners and other checkers in a manner similar to routine practice in the laboratory.

While advanced practitioners will act under the direction of the consultant pathologist, they will not be under his or her direct supervision. It is therefore appropriate that they should be considered, from an EQA point of view, with medical practitioners. Any references in the SOPs to medical staff should therefore be taken to apply also to ABMSPs in cervical cytology.

10.2.3 Medical staff

The two major activities undertaken by most pathologists in routine practice in the NHSCSP are the reporting of slides referred from primary screeners and checkers as potentially abnormal and the review of slides previously reported as negative or inadequate by primary screeners or checkers and which have later been identified as needing medical review. The EQA scheme for pathologists will therefore assess performance in providing an opinion on cases identified as potentially abnormal, and also in reviewing negative and inadequate slides that have been through primary screening. Primary screeners and checkers may wish to participate in this type of EQA in addition to their regular EQA, but their responses should not be used for performance assessment and should not be included in the analysis of this slide set.

EQA for medical staff should be based on slides that have been screened by primary screeners and checkers in a manner similar to routine practice in the laboratory. Practice varies between laboratories, but primary screeners and checkers often mark slides and therefore, if this is normal practice, this practice should be followed for EQA scheme purposes too. While pathologists and ABMSPs will know which slides would have been referred by screeners and checkers, they will not be told their opinion of the slides.

An example form to be used to identify potentially abnormal slides for EQA of medical staff is included at Appendix 1.

This type of EQA supports the professional work of the cytopathologist as defined by the British Society for Clinical Cytology's *Code of Practice for Cytopathology Laboratories*,¹⁰ namely that the cytopathologist should see all abnormal material and a proportion of negative material to ensure that accuracy and quality are being maintained. In addition, the pathologist should have experience in screening unmarked slides, and particularly of rescreening negative slides when subsequent abnormalities are found and of rescreening the whole slide before issuing a report when equivocal cell groups have been marked for an opinion. It is envisaged that in this EQA cytopathologists will examine the whole of every slide, including those that have been marked by primary screeners and checkers.

10.2.4 Trainee staff

Trainee cytoscreeners, trainee biomedical scientists and trainee medical staff who intend to work in the field of cervical cytology are encouraged to participate in EQA. The scheme is considered to be of purely educational value for these staff, and, although they should be allocated a mark, with the same feedback given to them as to qualified staff within the same peer group, their results should be excluded from any consensus calculation or performance analysis of the slide set.

11. SCORING OF RESPONSES (EQA D2, E1, E4.3, E5, F3.1, F4.2, F4.3 and G1)

11.1 Individual responses

All participants in the EQA scheme will register their opinion as regards cytological pattern and specific infections in a format consistent with standard BSCC reporting and the standard request form (HMR 101). An example response form is included at Appendix 2. The response from each participant will be scored by the EQA facilitator against the consensus diagnosis. Consensus results (calculated after the completion of the EQA round) are based on the valid responses of all eligible participants within a peer group, irrespective of whether or not they received pre-screened slides.

All individuals will be given confidential provisional feedback (interim feedback) as they participate in the circulation. This will allow individuals to compare their own responses with the submitted opinions for the slides.

11.2 Consensus opinion

The 'correct' answer will be based on a consensus opinion. Only slides which achieve a regional consensus diagnosis from 80% of participants in the relevant peer group (screener/checker and ABMSP/medical pathologist) reporting the slides will be used for personal performance monitoring. Although this will result in a delay in final feedback to participants, the problems in reaching agreement on cytological diagnosis warrant this approach. Where the consensus opinion differs from that of the submitting laboratory, the regional EQA facilitator will feed this back to the submitting laboratory.

The 'submitted' opinions on the slides will be released once all the staff within the laboratory have viewed and reported on the EQA slides.

Written interim feedback will be provided as soon as possible after participation.

Consensus agreement between negative, inadequate and abnormal slides will be based on all valid participant responses for the particular slide.

In the pathologists/ABMSPs peer group, consensus agreement on the grading of abnormal slides will be based on all valid pathologists'/ABMSPs' opinions for the slide. Amalgamation of 'adjacent' grades of nuclear abnormality (eg borderline change and mild, mild and moderate, moderate and severe) will be permitted, if necessary, to achieve an 80% consensus diagnosis. Glandular abnormalities may be combined with severe dyskaryosis or ?invasive carcinoma.

Only individuals with responsibility for the issuing of reports will be included in the consensus agreements. Trainees will be encouraged to participate in the scheme but their opinions will not contribute to the consensus diagnosis.

11.3 Assessment of performance

At the end of the circulation, formal scores can be determined by comparing participant responses and slide consensus. The formal assessment of personal performance differs for the two peer groups of participants.

11.3.1 Primary screeners and checkers

Personal performance will be formally assessed on the distinction between negative, inadequate and abnormal slides and any instances of missed dyskaryosis [significant screening error (SSE)]. Quantitative and qualitative feedback will, however, be provided for personal educational purposes on the grading of abnormalities. Qualitative feedback will be provided on the identification of infections.

11.3.2 Pathologists/ABMSPs

Personal performance will be assessed on the distinction between negative, inadequate and abnormal slides, the grading of cytological patterns for abnormal samples and any instances of missed moderate or worse cytology [clinically serious error (CSE)]. Qualitative feedback will be provided on the identification of infections.

11.4 Marking scheme

The marking scheme, presented in detail in Appendices 3 and 4, is as follows.

11.4.1 All staff

For the distinction between negative, inadequate and abnormal – either 0 (zero) for a wrong answer or 2 (two) marks for a correct answer. Consensus results are based on valid responses from all qualified participants reporting the slide set, for both the screener/checker set(s) and the pathologist/ABMSP set(s).

11.4.2 Non-medical staff

The responses of non-medical staff are used only to assess non-medical staff. Primary screeners and checkers will receive feedback on the grading of abnormalities but this will not be used to calculate their score.

11.4.3 Medical staff

An additional mark is given with respect to grading of abnormalities. If

the response lies within the 80% consensus at the same peer level, then a mark of 2 (two) is awarded.

If the grading lies 'one grade away' from the consensus answer, then a mark of 1 (one) is allocated. If the grading lies more than one adjacent grade away, then zero marks are allocated.

With regard to the marking of ?glandular neoplasia, 2 (two) marks are given for a correct response of glandular neoplasia if that is the 80% consensus. If the 80% consensus is ?glandular neoplasia then 1 (one) mark is given for severe dyskaryosis or ?invasive. No marks are given for other degrees of abnormality.

Only medical staff/ABMSP responses are used to assess medical staff/ABMSP grading.

11.5 Identification of substandard and persistent substandard performance

Substandard performance can be identified by placing the scores for each individual peer group in each circulation into rank order and noting the participant code numbers of those with scores below the 2.5th centile. Further to this, an occurrence of a clinically serious error (pathologists/ABMSPs) or a significant screening error (screeners/checkers) in a round will mean the participant has substandard performance.

The first action point occurs when a participant is identified as having persistent substandard performance. This is acknowledged as an occurrence of any of the following two situations in two out of three rounds:

- scoring below the 2.5th centile point
- making a CSE or SSE, as defined under SOP 10.

If a participant makes two or more CSEs/SSEs in one round or makes one or more of these errors and falls below the 2.5th centile point in a single round, this will not constitute persistent substandard performance on the basis of that round alone.

The second action point occurs if a participant's performance continues to be substandard or if he or she makes a CSE/SSE in two out of three successive circulations after triggering the first action point. Failure to participate in a circulation (for reasons other than legitimate long term absence) after reaching the first action point will be regarded as a score below the 2.5th centile. The three consecutive circulations should be counted on a 'rolling' basis, with calculation of performance based on the three most recent circulations.

12. FINANCIAL ASPECTS

Funding of the EQA scheme is included in the budget for regional quality assurance. Subscriptions are therefore not required from NHS laboratories for participation in the scheme.

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Standard Operating Procedure 1

Maintenance of protocols and standard operating procedures (EQA A1.6, A2, A4, A9, B1, B8, D2, E1, E2.3, E2.4, G1, H1, H2, H3, H4 and H5)

The steering committee (national coordinating group for laboratory QA) will meet at least twice yearly and will conduct an annual management review of the quality management system and all its services to identify required changes to meet the needs of the participants and actions required to ensure the continuation of the service. Annual reports will be produced and copies will be submitted to NQAAP and the RCPATH Steering Committee for EQA in Histopathology/Cytopathology, facilitators and participants. A copy of the executive summary of the annual management review report will be forwarded to CPA.

There will be formal arrangements and meetings between relevant QARC staff and the regional EQA organising committee (the regional coordinating group responsible for laboratory QA). Within a region, the scheme should be discussed by the participants and an annual report should be submitted to the regional QARC. In addition to the regional annual report, each region will submit data/information according to the national proforma to the national office for discussion at the steering committee meeting and to aid the compilation of the national reports. This information will include a summary of participant satisfaction and complaints recorded during the year.

The regional scheme organiser will review each SOP annually prior to submission of an annual report to the regional EQA scheme organising committee.

Proposals to amend an SOP will be submitted initially to regional groups and then, with regional support, to the national office of the NHSCSP for consideration by the national EQA subcommittee and steering committee.

The SOPs will be kept in a loose-leaf folder in the office of each regional EQA facilitator as a controlled document. A master set will be held by the NHSCSP national office. These will be controlled documents, with all amendments to the SOPs signed and dated.

Signed (Regional scheme organiser)

Dated

Standard Operating Procedure 2

Scheme membership (EQA E3, E5.1 and G1)

Participation in EQA is mandatory for all staff working in the NHSCSP who report gynaecological cytopathology samples (cytoscreeners, biomedical scientists, ABMSPs and pathologists).⁶ *Quality Assurance Guidelines for the Cervical Screening Programme*, published in 1996, recommended as a quality standard that all staff screening or reporting cervical cytology should participate in EQA (proficiency testing as it was known then) and demonstrate an acceptable performance.¹¹ This scheme applies to both permanent and temporary staff reporting cervical cytology taken through the NHSCSP.

Locums should ensure that they participate regularly in one regional scheme and will be required to provide evidence of such participation.

A participant who moves between regions/schemes, whether permanently or on a locum basis, must be willing to provide dates of participation and EQA results for their last two rounds to enable the regional EQA facilitator to manage any subsequent persistent substandard performance or non-participation. If these results are not provided the facilitator will inform the medical/scientific lead in the employing laboratory as appropriate.

Students and trainees who intend to pursue a career that includes cervical cytology may also participate, but their scores will be excluded from the performance analysis.

Staff working in private laboratories where screening is undertaken for the NHS are required to participate in the scheme. Staff working in private laboratories where only private screening is performed are not required to participate; however, they are welcome to do so if they wish.

The primary purpose of EQA is to improve standards through education. However, in carrying out this endeavour, from time to time, underperformance by a participant may be recognised and action to investigate and, if necessary, to correct this will have to be taken. EQA does not fully replicate the routine clinical situation and has only limited use as a means for assessing clinical competence. As stated in EL(98)2,⁶ EQA schemes should complement the other systems in place for the early identification of potential problems which might affect patient care, and the identification of individual persistent poor performance through the EQA scheme will probably be exceptional. In this event, the results of the EQA scheme should not be interpreted or used in isolation, but should, like clinical audit, be part of laboratory quality assurance activities and local arrangements for clinical governance.¹²

Signed (Regional scheme organiser)

Dated

Standard Operating Procedure 3

Enrolment of new participants (EQA E5.1 and G1)

Prospective participants will be directed to the current on-line version of the scheme protocol and standard operating procedures, or forwarded a paper copy if specifically requested. They are asked to read this document and confirm in writing that they agree to its terms. Once such confirmation is received by the regional EQA facilitator, a participant code number will be issued and this code will not be known to the regional scheme organiser.

These data will be held securely and confidentially in the QARC.

Participants will also be asked to agree in writing to any changes to the protocol and SOPs that have been approved by NQAAP and the RCPATH Steering Committee for EQA in Histopathology/Cytopathology, prior to implementation.

Signed (Regional scheme organiser)

Date

Standard Operating Procedure 4

Obtaining case material (EQA A10, D3, E6, F2.1 and G1)

All laboratories which are currently performing satisfactorily (not at a national action point) in the *External Quality Assessment Scheme for the Evaluation of Papanicolaou Staining in Cervical Cytology*⁹ will be required to submit good examples to the QARC.

Slides submitted by the laboratory should have a diagnosis that has been agreed by at least a primary screener, a checker and a pathologist or ABMSP.

Prior to inclusion in the EQA round, all slides will be panel reviewed to ensure technical adequacy. The panel must also reach an agreed opinion on the classification of the slide. This opinion must be consistent with that of the submitting laboratory and patient history or histology as appropriate.

Signed (Regional scheme organiser)

Dated

Standard Operating Procedure 5

Initiating a circulation (EQA A10, D3, F2.3 and G1)

Slide sets will be assembled by the regional EQA facilitator, using slides agreed as acceptable by panel review, according to the *External Quality Assessment Scheme for Gynaecological Cytopathology Handbook for Facilitators*.⁵

Explanatory details and response sheets for each participant will accompany the delivery of the slide sets. An example of a referral sheet for medical staff including initial opinions from primary screeners and checkers is included at Appendix 1.

The regional EQA facilitator will liaise with laboratories over the delivery and return of the slide sets and a closing date will have been given for receipt of responses.

It may be necessary for some laboratories to participate in an EQA round provided by another region, to ensure that they receive slides in the chosen technology. In such instances, performance of each participant will be fed back to the local facilitator, who will manage any instances of persistent substandard performance or non-participation.

Participants who are unable to participate on agreed dates due to prearranged annual leave or illness, for example, may participate within another laboratory in the region. If this is not possible then one further mutually agreed date for participation will be offered within the month of completion of the planned circulation.

Written records shall be kept of which slides have been used by which laboratory and on which dates.

Signed (Regional scheme organiser)

Dated

Standard Operating Procedure 6

Confidentiality (EQA A1.4b, D2, E3.4, F3.1 and G1)

Responses from participants will be identified only by the participant code number. The code numbers allocated to participants by the regional EQA facilitator will be held in a locked cabinet or password protected file and will be accessible only to the EQA facilitator.

The regional scheme organiser will communicate with participants only by their code number, through the EQA facilitator, and will remain unaware of individual identities, as will the national organiser and national scheme secretary.

The link between a participant's name and code number may be divulged by the EQA facilitator to the regional organiser only in the case of the second action point being reached following persistent substandard performance in the EQA scheme (see SOP 10).

Any confidential material from the regional organiser is passed to the EQA facilitator with only the relevant code number exposed, such that the communication is placed in an appropriately addressed envelope by the facilitator without the facilitator having to read the contents of the communication.

The link between participant names and code numbers may be divulged by the EQA facilitator under only two circumstances:

1. In writing to a participant who requests a reminder of his or her code number. Code numbers must not be divulged by telephone.
2. In writing to the chair of NQAAP in order to investigate appropriately a case of persistent substandard performance in the EQA scheme under the terms of SOP 10.

No EQA result may be divulged to any other authority – see Executive Letter EL(98)2.⁶

All communications between the QARC and participants will be treated as confidential.

Signed (Regional scheme organiser)

Dated

Standard Operating Procedure 7

Receipt and analysis of EQA responses (EQA A1.4b, D2, F2.3, F3.1 and G1)

A participant's responses to a slide set will be returned to the regional EQA facilitator in a confidential manner, for example in a sealed envelope. An example of a response form is given at Appendix 2.

Responses must be given using standard BSCC terminology.

The regional EQA facilitator will analyse the individual results, and, together with the regional scheme organiser, will prepare the regional results. These will be reported to the regional organising committee and the region will make a report to the national coordinating group for laboratory QA in its capacity as national steering committee.

Signed (Regional scheme organiser)

Dated

Standard Operating Procedure 8

Participants' meetings (EQA A2, A11, G1, G2, H1.1 and H2)

A regional meeting of participants will be held at least annually. This will allow participants to comment on and contribute to the EQA scheme.

At the meeting, a summary of all results comparing consensus across the region with known or expected outcomes may be given. Slides may be available for viewing and discussion at the meeting. Nationally, a comparison will be prepared of each region's performance.

Signed (Regional scheme organiser)

Dated

Standard Operating Procedure 9

Feedback to participants (EQA D2, F5.1, F5.4, G1 and G2.4)

The regional EQA facilitator will issue written interim feedback to individuals as soon as possible after participation, detailing their performance compared with the submitted classification. The report will include the participant's code number and the envelope will be marked 'personal and confidential'.

At the end of the circulation a final report will be given, comparing the participant's responses with the consensus.

Consensus results can be available only when all participants have reported the slides. Personal reports, together with anonymised results for all participants, are then printed by the regional EQA facilitator, who posts them to the appropriate participants, along with any general communication which the regional organiser deems necessary.

After the individual scores have been calculated, the EQA facilitator checks the database to determine whether any of the participants fulfil the criteria of persistent substandard performance. The facilitator may also send a cumulative analysis of the participant's results to allow recognition of trends in performance.

Signed (Regional scheme organiser)

Dated

Standard Operating Procedure 10

Persistent substandard performance (EQA A1.4, B1, D2, E1, E2.3, E4.3, E5, F4.2, G1, G2.1 and G2.2)

Action points and the remedial measures taken when action points are reached are defined by the National Quality Assurance Advisory Panel (NQAAP) (histopathology and cytopathology).

Action points

The first action point occurs when a participant is identified as having persistent substandard performance. This is acknowledged as an occurrence of any of the following in two out of three consecutive rounds:

- Scoring below the 2.5th centile point. After each circulation has been scored, scores are put into rank order. Participant code numbers below the 2.5th centile are recorded.
- Making a clinically serious error (pathologists/ABMSPs only). This constitutes calling negative or inadequate a slide of which the consensus opinion is moderate dyskaryosis or worse.
- Making a significant screening error (screeners/checkers only). This constitutes calling negative or inadequate a slide of which the consensus opinion is mild dyskaryosis and worse.

Where a participant makes two or more clinically serious errors/significant screening errors in one round or makes one or more of these errors and falls below the 2.5th centile point in a single round, this will not constitute persistent substandard performance on the basis of that round alone.

Failure to participate in two out of three consecutive circulations, except for legitimate long term absence, should lead to the person ceasing to report cervical cytology, and therefore non-participation will be reported by the facilitator to the regional scheme organiser/laboratory QA lead and regional QA director. The organiser should also inform the chair of NQAAP.

The second action point occurs if a participant's performance continues to be substandard, ie his or her score falls below the 2.5th centile, or if he or she makes a clinically serious error/significant screening error in two out of three successive circulations after triggering the first action point. In addition, failure to participate in a round after the first action point is triggered will also be counted as a score below the 2.5th centile. The three consecutive circulations should be counted on a 'rolling' basis, with calculation of performance based on the three most recent circulations. A participant whose performance in both of the last two rounds resulted in the first action point being reached will not reach the second action point if his or her performance in the current round is satisfactory.

Individual and laboratory participation certificates are printed and distributed with the analysis of results.

Medical staff/ABMSP

A pathologist who reaches the first action point will receive a 'Dear Colleague' letter from the regional organiser. The letter will be sent from the regional EQA facilitator's office, using the confidential personal code number, so that the regional organiser remains unaware of the identity of the recipient of the letter. This would follow discussion between the organiser and the facilitator. However, if the prospective recipient is the regional organiser, then the facilitator should act on his or her own initiative.

The recipient will be asked to reply to the regional organiser within four weeks, through the EQA facilitator, and identified only by his or her personal code number, confirming that the letter has been received, offering an explanation and suggesting a remedy. When the first action point is reached, the facilitator will record the fact and the subsequent actions against the participant's code number. If an acknowledgement is not received within four weeks, the regional organiser will write again.

When the second action point is reached, the regional organiser will inform the chair of NQAAP, who will convene an appropriate investigation panel. The chair of NQAAP has the discretion to co-opt a respected local pathologist, such as the local scheme organiser or QA director if this is a pathologist. The regional organiser will provide the panel chair and the participant with details of the EQA responses which have resulted in this referral. This will be done anonymously through the EQA facilitator. The task of the investigation panel is to determine whether the low EQA scores relate to standards of routine practice that may put patient care at risk. The investigation will therefore seek all possible explanations of the low scores, including a review of the EQA scheme, but will concentrate on the participant's routine practice, working conditions and workload. The emphasis will be on identifying problems and implementing remedial measures rather than on punitive action. The chairman of the panel will correspond with the participant. This can initially be done anonymously through the EQA facilitator. These steps should be completed within four weeks at most. If the chair of the investigation panel is not satisfied that there is a reasonable explanation for the poor performance, or if lack of cooperation from the participant appears to be slowing the investigation, the participant's name can be released and the chair of the Joint Working Group on Quality Assurance will be informed and will refer the matter to the Professional Performance Panel of the Royal College of Pathologists and the trust medical director. The Professional Performance Committee will convene a review by a panel of three of the pathologist's peers, one of whom will have been selected by the pathologist under review.

Non-medical staff

At the first action point, the regional organiser will write to the participant, with a copy of the letter going to the laboratory scientific head for cervical cytology. The participant will be required to identify him- or herself to the scientific head in order to enable an action plan to be implemented. The laboratory scientific head must inform the lead consultant for the cytology service and the medical head of department. If it is the scientific head whose performance is in doubt, the copy letter should go to the consultant pathologist with responsibility for reporting cervical cytology. The regional scheme organiser will expect confirmation that this has occurred, including a copy of the agreed action plan, from the laboratory scientific head or medical head of department as appropriate within four weeks. If this is not received to the satisfaction of the organiser, a reminder is sent.

On reaching the second action point the NQAAP chair will be informed and will liaise with the regional QA director about further action.

Signed (Regional scheme organiser)

Dated

Standard Operating Procedure 11

Communications and complaints (EQA A2, A9, A11, B1, C1.4, E2.4, G1, G2 and H2)

All written communication with the regional EQA facilitator, the regional scheme organiser and the QA team or reference centre relating to EQA will be stored according to the retention times outlined by the Royal College of Pathologists and the Institute of Biomedical Science, in *The Retention and Storage of Pathological Records and Archives*.¹³ If a telephone or verbal communication is made, the organiser or facilitator receiving the communication will make a written note summarising the communication and the note will be dated and stored in the file.

A questionnaire will be circulated by facilitators to participants on an annual basis in order to gain feedback and assess the needs and requirements of users.

Complaints from individuals or laboratories about the organisation of the EQA scheme may be detailed in the questionnaire or made separately to the regional organising committee via the EQA facilitator or the regional EQA organiser.

Where the communication may be construed as a complaint, the action taken to remedy the complaint will be recorded, dated and clipped to the original communication in the file. If the regional organiser judges the complaint to be justified and of a nature which requires any alteration in the procedures of the scheme, the preferred sequence of events for enacting such changes would be:

1. consideration by the regional organising committee and recommendation to the national office of the NHSCSP
2. discussion at the EQA subcommittee meeting and possible referral for approval to the scheme steering committee
3. discussion/approval of the revision by the steering committee
4. production of a draft revision to the relevant SOP
5. implementation of the revision pending approval by the RCPATH Steering Committee for EQA in Histopathology/Cytopathology and NQAAP
6. notification of the revision to facilitators, participants, the RCPATH Steering Committee for EQA in Histopathology/Cytopathology and NQAAP.

In the event of a complaint being handled locally to the dissatisfaction of a participant, the participant can complain directly to the national scheme organiser. Should satisfaction still not be obtained, then the participant can complain directly to the chair of the RCPATH Steering Committee for EQA in Histopathology/Cytopathology.

Signed (Regional scheme organiser)

Dated

Standard Operating Procedure 12

Oversight (EQA A1, A2, A3, A4, A5, A6, A7, A8, A9, A10, A11, B8, E1, E2.3, E2.4, G1, G2, H1, H2, H3, H4 and H5)

EQA scheme management will be responsible for setting, reviewing and revising the objectives of the scheme. The scheme will demonstrate its commitment to participants by establishing a quality policy and a quality management system and by performing annual management reviews. Regional quality assurance reference centre management shall ensure the availability of necessary resources for the efficient running of the scheme.

The annual management review shall include regional reports/data, assessments of participant satisfaction and complaints, internal audits of the quality management system, internal audits of EQA scheme operation, status of preventative, corrective and improvement actions, major changes in organisation and management, resource or procedure and the follow up of previous management reviews.

Comments on the mode of operation of the scheme are invited at every participants' meeting. Changes proposed at such meetings will normally be reviewed by the regional organising committee followed by the EQA subcommittee/steering committee and then by the RCPATH Steering Committee for EQA in Histopathology/Cytopathology and NQAAP, as described in SOP 11. Suggestions for a change of the scheme organiser should be discussed first at the participants' meeting; such suggestions must be considered if made by any scheme member. As far as possible, decisions taken at the participants' meeting should be made on a democratic basis by those present.

The annual management review report will be provided to the RCPATH Steering Committee for EQA in Histopathology/Cytopathology and NQAAP. It will include a summary of the national results and include details of any changes in how the scheme runs, actual or planned, proposed by the steering committee. Specifically, any changes in these SOPs will be reported, as will any changes in the assessment procedure, changes in procedures for managing substandard performance in the round(s) since the last report, actual or planned, and also the number of participants who triggered action in response to substandard performance in the previous year. A copy of the executive summary of the report will be forwarded to CPA (UK) Ltd.

Signed (Regional scheme organiser)

Dated

Standard Operating Procedure 13

Managerial accountability (EQA A1.1, B6, B7, B8, C1, C2, C3 and C4)

The scheme operates from within the regional quality assurance reference centres. At least one is located in each region. These are overseen by the regional quality assurance director, who is accountable to the regional director of public health.

The national scheme is overseen from the national office of the NHSCSP. The Director of the NHSCSP is accountable to the Department of Health.

Signed (Regional scheme organiser)

Dated

Standard Operating Procedure 14

Finance

The costs for oversight of the scheme at a national level are included in the budget of the NHSCSP national office.

The costs of running the scheme and its supervision at a local level are included in the budget of the regional quality assurance reference centre.

The costs incurred by laboratories or individuals in participating in a scheme, such as travel to a participating centre for a locum to participate when not employed by that centre, must be borne by those laboratories or individuals.

Signed (Regional scheme organiser)

Dated

Standard Operating Procedure 15

Staffing (EQA A1.4, B1, B2, B3, B4, B5, B6 and B7)

The national scheme organiser is the chair of the National Laboratory QA Group (steering committee) and this role is a function of the post of chair of the National Laboratory QA Group, which is held for a period of three years.

The scheme secretary is Mrs Julietta Patnick, Director, NHS Cancer Screening Programmes. Administration of the scheme and the national quality manager is provided by the national office of the NHSCSP.

The regional scheme organiser will hold a senior post in a laboratory providing gynaecological cytopathology for the NHSCSP and will have appropriate training and experience. The regional organiser should be a participant in the EQA scheme and should be appointed following consultation with regional scheme participants.

The EQA facilitator will be appointed by the regional QA director.

Signed (Regional scheme organiser)

Dated

Standard Operating Procedure 16

Training (EQA A1.4, B2, B3, B4 and B8)

The regional EQA facilitator is involved in a general training programme as a part of employment. The NHSCSP provides a regular meeting forum and support for all regional facilitators.

Signed (Regional scheme organiser)

Dated

APPENDIX 1: REFERRAL OF ABNORMAL SLIDES FOR REPORTING FORM

Comment

Referral for reporting is on the basis that the slides indicated are, in your opinion, potentially or probably abnormal. You will not be marked on the basis of your responses on this form. Please treat the slides as you would in normal practice within your laboratory (for example, ringing, dotting or marking as appropriate).

Primary screener

If you are a primary screener, please indicate by 'R' those slides you would refer to a checker or pathologist for reporting on the basis of your opinion. The pathologist will examine the slide according to his or her normal practice and form his or her own opinion.

Checker

If you are a checker, please indicate by an 'A' those slides you would refer to a pathologist for reporting on the basis of your opinion. Please look only at those slides indicated as 'R' by the primary screener. The pathologist will examine the slide according to his or her normal practice and form his or her own opinion.

Hospital

Slide set identification

PLEASE MARK IN THE APPROPRIATE BOX

Slide number	1	2	3	4	5	6	7	8	9	10
Primary screener										
Checker										

APPENDIX 2: NHS CERVICAL SCREENING PROGRAMME EXTERNAL QUALITY ASSESSMENT SCHEME RESPONSE SHEET

Personal identity code:	
Date of participation:	
Slide set identity:	




You **must** tick one box and **only one box** in the Result column of the Cytological Pattern section for each slide. Failure to tick a box or ticking more than one box in any column in this section will be penalised as an overall or undercall as appropriate. Please complete the Additional Features section as appropriate.

Cytological pattern	Result										
	Slide number										
HMR 101 category	Result code	1	2	3	4	5	6	7	8	9	10
Inadequate HMR category	(1)										
Negative	(2)										
Borderline changes	(8)										
Mild dyskaryosis	(3)										
Moderate dyskaryosis	(7)										
Severe dyskaryosis	(4)										
Severe dyskaryosis/ ?invasive squamous carcinoma	(5)										
?Glandular neoplasia	(6)										

Additional features	Result										
	Slide number										
	1	2	3	4	5	6	7	8	9	10	
No infection present											
<i>Trichomonas vaginalis</i>											
Candida											
Wart virus											
Herpes virus											
<i>Actinomyces</i> like organisms											
Other											

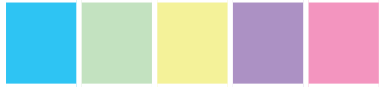
APPENDIX 3: SCORING MATRIX FOR SCREENERS/ CHECKERS

		CONSENSUS					
		NEGATIVE	INADEQUATE	ABNORMAL			
				INCLUSIVE OF BORDERLINE	DYSKARYOTIC		
RESPONSE	NEGATIVE	2	0	0	0		
	INADEQUATE	0	2	0	0		
	ABNORMAL	BORDERLINE	0	0	2		
		DYSKARYOTIC	Mild dyskaryosis	0	0	2	
			Moderate dyskaryosis	0	0	2	
			Severe dyskaryosis	0	0	2	
			?Invasive squamous carcinoma	0	0	2	
			?Glandular neoplasia	0	0	2	

	Slide correctly interpreted
	Slide incorrectly interpreted
	Slide incorrectly interpreted – significant screening error

APPENDIX 4: SCORING MATRIX FOR PATHOLOGISTS/ABMSPS

RESPONSE		CONSENSUS													
		Negative	Inadequate	Abnormal/ no grade	Borderline changes	Borderline changes/ mild dyskaryosis	Mild dyskaryosis	Mild dyskaryosis/ moderate dyskaryosis	Moderate dyskaryosis	Moderate dyskaryosis/ severe dyskaryosis	Severe dyskaryosis	Severe dyskaryosis/ ?invasive squamous carcinoma	Severe dyskaryosis/ ?glandular neoplasia	?invasive squamous carcinoma/ ?glandular neoplasia	?glandular neoplasia
Negative	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Inadequate	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0
Borderline changes	0	0	2	4	3	2	2	2	2	2	2	2	2	2	2
Mild dyskaryosis	0	0	2	3	4	3	3	3	2	2	2	2	2	2	2
Moderate dyskaryosis	0	0	2	2	3	4	4	3	3	3	3	3	2	2	2
Severe dyskaryosis	0	0	2	2	2	3	3	3	4	4	4	4	3	3	3
?invasive squamous carcinoma	0	0	2	2	2	2	2	2	3	4	4	3	4	4	3
?glandular neoplasia	0	0	2	2	2	2	2	2	2	3	4	4	3	4	4



Slide correctly interpreted

One grade from consensus opinion

More than one grade from consensus opinion

Slide incorrectly interpreted

Slide incorrectly interpreted – clinically serious error

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