

## **External Quality Assessment Scheme for Gynaecological Cytopathology**

---

Protocol and Standard Operating Procedures

Version 4



## *Cancer Screening Programmes*

# External quality assessment scheme for gynaecological cytopathology

---

Protocol and standard operating procedures  
Version 4

**Editor****Sharon Whitehurst**

NHSCSP Cytology Education Manager  
Room 5087, 5th Floor  
Department of Pathology  
Duncan Building  
Royal Liverpool & Broadgreen University Hospital NHS Trust  
Daulby Street  
Liverpool  
L69 3GA

Tel: 0151 706 4519/0151 706 4579

Fax: 0151-706 5796

Email: Sharon.Whitehurst@rlbuht.nhs.uk

**Published by****NHS Cancer Screening Programmes**

Fulwood House  
Old Fulwood Road  
Sheffield  
S10 3TH

Tel: 0114 271 1060

Fax: 0114 271 1089

Email: [info@cancerscreening.nhs.uk](mailto:info@cancerscreening.nhs.uk)

Website: [www.cancerscreening.nhs.uk](http://www.cancerscreening.nhs.uk)

© NHS Cancer Screening Programmes 2011

The contents of this document may be copied for use by staff working in the public sector but may not be copied for any other purpose without prior permission from NHS Cancer Screening Programmes.

This document contains 6 prelim pages and 35 pages of text. It is available in PDF format on the NHS Cervical Screening Programme intranet site.

# CONTENTS

ACKNOWLEDGEMENTS	V
PROTOCOL	1
1. Introduction	1
2. General description of the EQA scheme	1
3. Scope of the scheme	1
4. Objectives of the scheme	1
5. Joint working group for quality assurance	2
6. EQA scheme organisation	2
6.1 NHS Cervical Screening Programme (scheme provider)	3
6.2 National scheme organiser	3
6.3 EQA scheme steering committee	3
6.4 Scheme secretary	3
6.5 National quality manager	3
6.6 Operation of the scheme	3
6.7 Regional organiser	4
6.8 Regional EQA scheme organising committee	4
6.9 Regional EQA facilitator	4
6.10 Regional quality manager	5
6.11 Relationships within the scheme	5
7. Participation	7
8. Circulation of cases	7
9. Selection of cases	7
10. Operation of the Scheme	9
10.1 Conditions for examining EQA slides	7
10.2 Routine practice and marking of slides	9
11. Scoring of responses	11
11.1 Individual responses	11
11.2 Consensus opinion	11
11.3 Assessment of performance	12
11.4 Marking scheme	12
11.5 Identification of substandard and persistent substandard performance	13
12. Financial aspects	13
STANDARD OPERATING PROCEDURES	14
1. Maintenance of protocols and standard operating procedures	15
2. Scheme membership	16
3. Enrolling new participants	17
4. Obtaining case material	18
5. Initiating a circulation	19
6. Confidentiality	20
7. Receipt and analysis of EQA responses	21
8. Participants' meetings	22
9. Feedback to participants	23
10. Persistent substandard performance	24
11. Communications and complaints	26
12. Oversight	27
13. Managerial accountability	28
14. Finance	29
15. Staffing	30
16. Training	31

---

REFERENCES	32
APPENDIX 1 Referral of abnormal slides for reporting form	33
APPENDIX 2 NHS Cervical Screening Programme external quality assessment scheme response sheet	33
APPENDIX 3 Scoring matrix for screeners/checkers	34
APPENDIX 4 Scoring matrix for pathologists/ABMSPs	35

## ACKNOWLEDGEMENTS

This updated and amended version of the *Protocol and Standard Operating Procedures* reflects the evolution of the External Quality Assessment Scheme for Gynaecological Cytopathology since its introduction in the English Cervical Screening Programme in 1998, and the many comments and issues raised during its operation. The editor is especially grateful to the National Laboratory Quality Assurance (QA) Group, members of the EQA subcommittee of the National Laboratory QA Group and regional facilitators for their contributions to the success of the scheme.

---

# 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. Facilitating this is an independent system of checking laboratory results by an external agency. The system delivers an acceptable degree of reliability and consistency by educating, advising and supporting all participants.

EQA, or proficiency testing as it has been known, was first introduced into the cervical screening programme when the Department of Health Advisory Committee on the Assurance of Laboratory Standards published the *Protocol for a Proficiency Test Scheme in Gynaecological Cytopathology*<sup>1</sup> in 1988. Regional schemes were subsequently developed. Although the principles of these schemes were similar, each region developed its own interpretation and methodology.

A national EQA scheme has now been introduced, based on *Recommendations for the Development of Histopathology/Cytopathology External Quality Assessment Schemes*.<sup>2</sup> It was developed by the Working Group on Histopathology External Quality Assessment Scheme Accreditation and implemented in 1998. The recommendations of the Working Group were endorsed by The Royal College of Pathologists. Where appropriate, the protocol also drew on the successful experience of the EQA scheme in breast screening pathology, in use in the NHS Breast Screening Programme.

In its original form (set out in the first version of this publication) the EQA scheme was adopted nationally for the 2004/05 screening round. Later versions of this document reflect amendments made to the scheme in the light of feedback from regional Quality Assurance Reference Centres and participants. This protocol and its standard operating procedures should be read in conjunction with the *Standards for EQA Schemes in Laboratory Medicine*.<sup>3</sup> References to the standards appear in brackets as follows '(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) set out here 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. These objectives are to

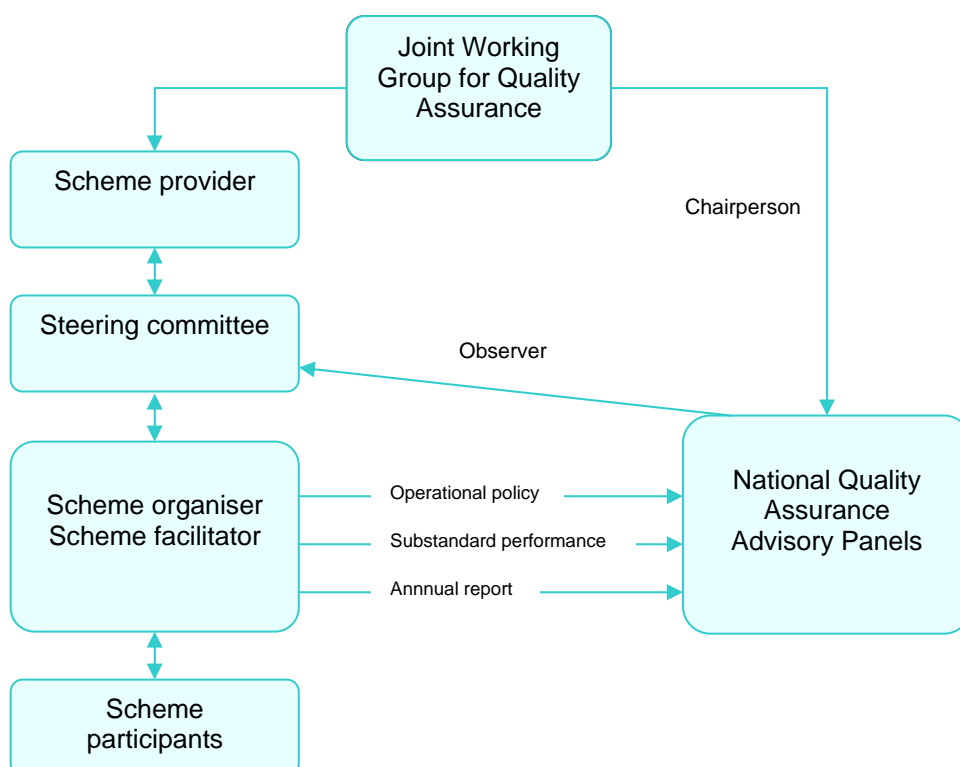
- provide an external assessment of the quality of reporting of cervical cytology samples

- maintain and improve quality by achieving consistent good practice
- promote education and training through formal feedback
- identify substandard performance and its causes, enabling remedial action to be taken
- 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 Assurance<sup>4</sup> (JWG) is recognised by the Department of Health (DH) as the independent body responsible for pathology EQA in the United Kingdom (see 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) a wholly owned subsidiary of the United Kingdom Accreditation Service. The JWG's remit is to oversee all EQA in the UK, to approve and register schemes, to set policies and to maintain appropriate professional standards. It 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.

**Figure 1** Pathology EQA in the UK



## 6. EQA scheme organisation (EQA A1, A3, A4, A5, A7, B1.1, B2, B8, E2, H1, H2, H3, H4 and H5)

### 6.1 NHS Cervical Screening Programme (scheme provider)

The NHS Cervical Screening Programme (NHSCSP) forms part of NHS Cancer Screening Programmes. Contact details for their national office are as follows

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

### 6.2 National scheme organiser

The organiser of the scheme at a national level is the chair of the English national coordinating group for laboratory quality assurance (QA), who also participates in the scheme.

### 6.3 EQA scheme steering committee

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

### 6.4 Scheme secretary

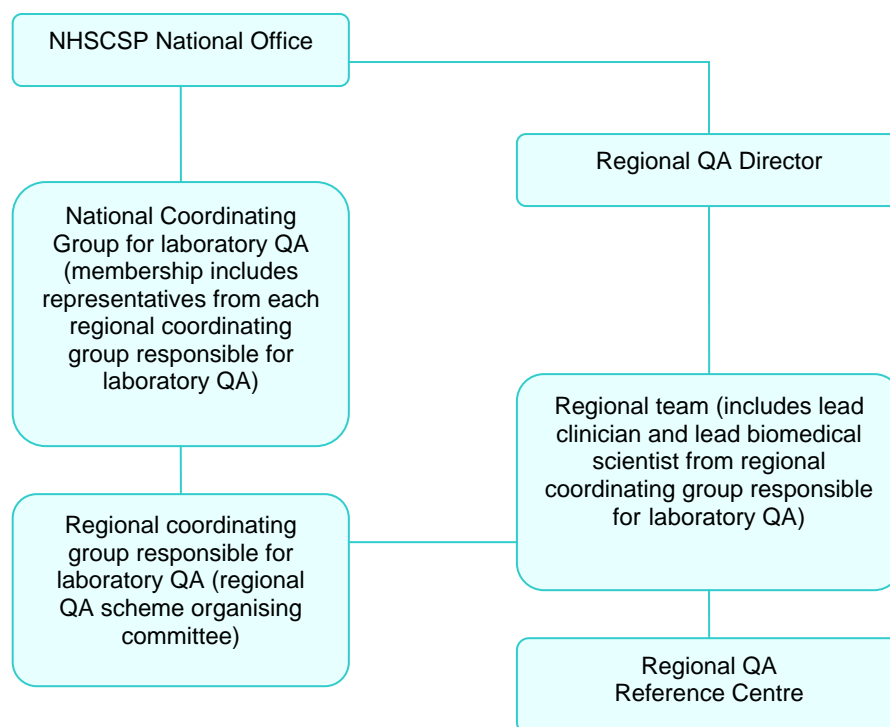
The secretariat for the national scheme is provided by the national office of the NHSCSP.

### 6.5 National quality manager

A national quality manager provided by the national office of the NHSCSP ensures that the scheme's quality management system functions correctly. The national quality manager is responsible to the national organiser, but is not him or herself the national organiser.

### 6.6 Operation of the scheme

Owing to the large number of participants nationally and to the nature of cervical cytology (which does not currently allow the production of multiple identical specimens) the national scheme is implemented on a regional basis. The scheme is organised through the regional quality assurance framework of the NHSCSP (Figure 2) and a *Handbook for Facilitators*<sup>5</sup> 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 the regional organiser, who also participates in the scheme. It is recommended that this individual be the chair of the regional coordinating group responsible for laboratory QA.

### 6.8 Regional EQA scheme organising committee

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

### 6.9 Regional EQA facilitator

A regional QA facilitator undertakes the day-to-day running of the scheme at a local level. Based at the regional quality assurance reference centre (QARC), he or she acts as the regional EQA scheme secretary and is responsible for ensuring that the scheme operates efficiently. Key duties include

- identification of participants
- organisation of slide sets
  - collection of slides
  - arranging the review of submitted slides
  - assembly of slide sets
- delivery and collection of slide sets
- analysis and interpretation of results
- feedback to participants
- dealing with instances of substandard performance
- record keeping.

An essential part of the role is to maintain the confidentiality of participants in the scheme, while allowing anonymous communication between the people involved in cases 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 is responsible to the regional organiser for the efficient running of the scheme; for other functions, responsibility is to the regional QA director who employs him or her. All regional EQA facilitators in England meet at least annually to discuss the scheme.

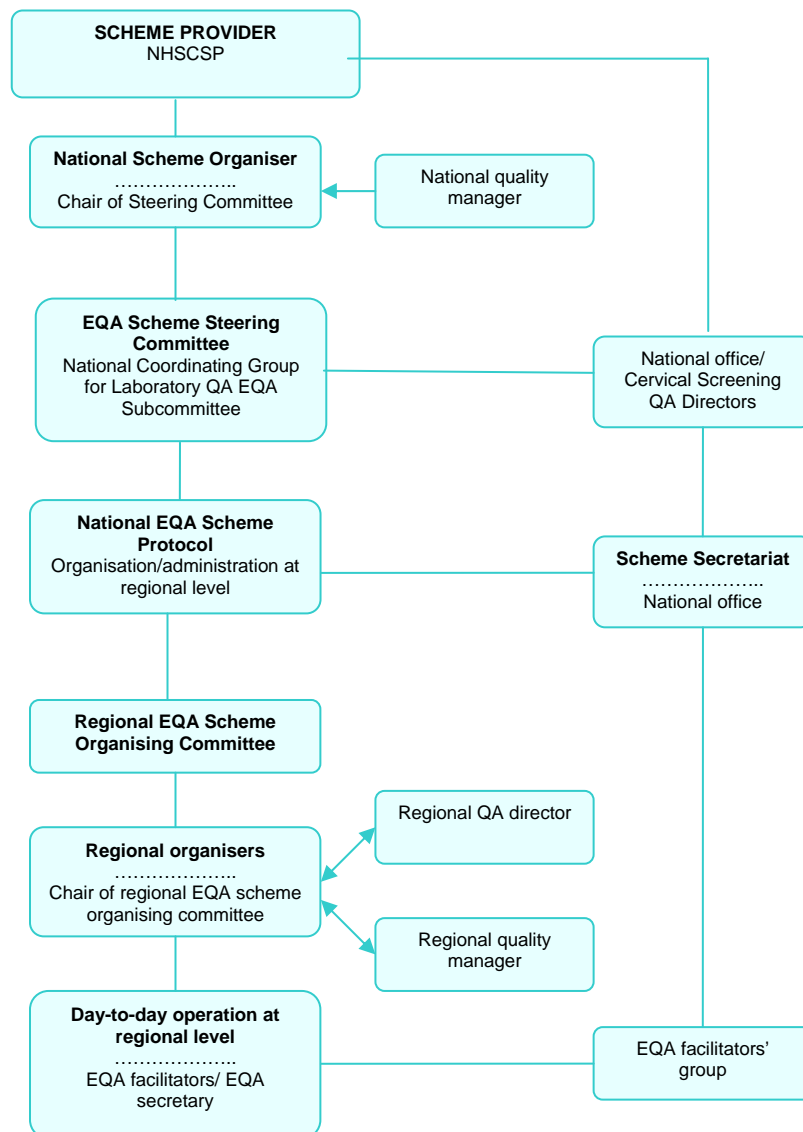
#### **6.10 Regional quality manager**

The regional quality manager ensures that the quality management system is effective at a local level and is responsible to the regional organiser, but is not him or herself 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) who report gynaecological cytology for the NHSCSP. Names, addresses and participant code numbers are recorded by the regional facilitator in the participant files, which are 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*)<sup>6</sup> makes participation in EQA schemes mandatory for staff delivering the NHS Breast and Cervical Screening Programmes. 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.<sup>7</sup>

## 8. Circulation of cases (EQA D3, E3, E4.2 and G1)

- a) There are 10 slides in each slide set per circulation and additional slides may be included for special educational interest.
- b) There are two rounds (ie circulations of slide sets) in each EQA year (April to March).
- c) Slides will be circulated to all laboratories participating in the NHSCSP. A full list of the laboratories is available at the national office and each QARC holds a list of those for which it is responsible.

## 9. Selection of cases

The slides will be good (but not necessarily easy) examples and may include all classifications recognised by the British Society for Clinical Cytology (BSCC)

- inadequate
- negative
- mild dyskaryosis
- moderate dyskaryosis
- severe dyskaryosis
- ?invasive squamous carcinoma
- ?glandular neoplasia
- borderline changes.

These classifications are explained in *Achievable Standards, Benchmarks for Reporting and Criteria for Evaluating Cervical Cytopathology*<sup>8</sup> Cases involving infections may also be included in EQA. The final composition of slide sets for circulation will be decided by the local facilitator in line with guidance published in the *EQA Scheme for Gynaecological Cytopathology Handbook for Facilitators*.<sup>5</sup> The cases circulated will be typical of routine practice and not rarities, although slide sets will need to include a higher proportion of abnormal cases than is seen routinely.

- a) Adequate clinical information will be provided by the laboratory submitting each slide, derived from the standard request form HMR101/5 or its electronic equivalent.
- b) All NHSCSP laboratories that are currently performing satisfactorily (ie not at a national action point) according to the *External Quality Assessment Scheme for*

*the Evaluation of Papanicolaou Staining in Cervical Cytology*<sup>9</sup> 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 liquid based 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 may be submitted by a laboratory; however, they should be considered as entirely separate cases for EQA purposes as it cannot be assumed that each will give rise to identical consensus.

Histology is obtained routinely only for samples showing a high grade abnormality (moderate dyskaryosis or worse). 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 that is to be included. Samples showing mild dyskaryosis must have been followed by a subsequent sample or a histological diagnosis consistent with the original report on the submitted slide. Borderline slides can legitimately be followed by a negative, low grade or high grade sample; consequently, any category of cytology except inadequate will be acceptable following this category. A negative slide will not need to be supported by a second negative slide. An inadequate slide 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 reviewing each one individually. Slides will be assessed for their technical quality, including stain quality, mounting and any cracks.
- d) Before accepting a slide into the scheme, and without knowing the diagnosis submitted, the panel must agree a classification that is consistent with the patient history or histology. Where the panel's opinion differs from the submitted diagnosis the facilitator will inform the laboratory and return the slide immediately: eg when there is disagreement between the diagnosis of negative, inadequate or abnormal, or when the degree of abnormality agreed by the panel would result in a higher-grade management recommendation for the woman. In such cases it is the responsibility of the medical head of the submitting laboratory to take any necessary follow-up action.
- 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 consent to their EQA performance being communicated to the local facilitator, who will manage any issues.
- f) The names of the patient and the submitting laboratory should be obscured for the purposes of the round. However, the identification should not be effaced from the slide. The laboratory is responsible for concealing the patient details on the slide before submitting it, while the facilitator will re-label the slides on receipt to ensure that details of the submitting laboratory are not visible during panel review or the round. The facilitator is expected to know the whereabouts of every slide, in case a patient's slide that has been included in the circulation needs to be located. Once the slide is no longer needed for EQA purposes it should be returned to its submitting laboratory at the end of the final round. 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 it reaches each laboratory in the circulation.

- g) The educational value of the scheme may be enhanced with 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 conditions similar to those used in their routine practice (ie not in examination conditions). However, participants must not discuss EQA slides in the laboratory until all mandatory participants (excluding absentees) have seen the slides and recorded and submitted their results. Senior members of staff should reiterate this on each occasion that EQA slides are to be reported, emphasising that any evaluation of personal performance is meaningless if discussion takes place. Such discussion reduces the value of EQA and may also propagate false responses, adversely affecting individual performance. Talking about the slides is encouraged once all mandatory participants (excluding absentees) have submitted their responses and before the slides leave the laboratory. Interlaboratory discussion of the slides or discussion with absentees prior to their participation is not permitted.

### 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. Staff whose laboratories routinely use more than one LBC system will be required to complete EQA for one system only, and assessment should alternate at each round between the systems.

All participants will receive feedback on all areas and not solely 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. At present, staff (other than ABMSPs) who are not medically qualified should not report abnormal slides; instead, they should sort slides into those that they will report themselves as negative or inadequate and those that will be passed on to more senior colleagues for further review. Non-medical staff are therefore assessed on this basis. However, many laboratories routinely encourage their non-medical staff to suggest a classification and checkers often require this. The scoring scheme described in section 11 is thus expected to extend to all staff to enhance the educational benefit of the scheme.

*Primary screening* Individuals (usually cytology screeners and biomedical scientists) who undertake primary screening decide whether a slide is negative, inadequate, or potentially abnormal and needing to be referred for reporting. Individuals who carry out 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, their responses will not be assessed or included in any consensus calculation or performance analysis for this slide set.

*Checking* Individuals who are experienced cytology screeners or biomedical scientists have variable duties. Checkers usually undertake some primary

screening, and should participate as primary screeners. However, there may be some checkers who undertake no primary screening at all, and normally receive marked slides. When participating in the EQA scheme, members of this group should have their slides marked by primary screeners who are themselves participating in the scheme.

#### *10.2.2 Advanced biomedical scientist practitioner (ABMSP) in cervical cytology*

The duties of ABMSPs include signing out abnormal slides and giving management recommendations. They may, in addition, undertake checking duties and report unchecked slides, effectively acting as their own 'checker'. EQA for these staff should be based on slides that have been screened by primary screeners and other checkers, in line with 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. From an EQA point of view, it is therefore appropriate that they be considered 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

- reporting slides referred from primary screeners and checkers as potentially abnormal
- reviewing slides that have previously been reported as negative or inadequate by primary screeners or checkers and have later been identified as needing medical review.

The EQA scheme for pathologists will therefore assess performance both in providing an opinion on cases identified as potentially abnormal and 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. However, their responses should not be used for performance assessment or 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 line with routine practice in the laboratory. Practice varies between laboratories, but primary screeners and checkers often mark slides and where this is normal practice it should be retained for EQA purposes. Pathologists and ABMSPs will know which slides have been referred by screeners and checkers, but not their conclusions.

Appendix 1 consists of an example form for use by medical staff when identifying potentially abnormal slides for EQA purposes. This type of exercise supports the professional work of the cytopathologist as defined by the British Society for Clinical Cytology's *Code of Practice for Cytopathology Laboratories*:<sup>10</sup> ie 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, in particular, 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 slides that have been marked by primary screeners and checkers.

#### *10.2.4 Trainee staff*

Trainee cytology screeners, trainee biomedical scientists and trainee medical staff who intend to work in the field of cervical cytology are encouraged to participate in EQA. However, the scheme is considered to be of purely educational value for these staff; although they should be allocated a mark and given the same level of feedback as qualified staff within their peer group, their results should thus 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 concerning 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 'submitted' opinions on the slides will be released once all mandatory participants (excluding absentees) within the laboratory have viewed the EQA slides and recorded and submitted their results. 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 personal and 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. Written interim feedback will be provided as soon as possible after participation, and ideally within two weeks.

### **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 facilitator will inform the laboratory and return the slide immediately: eg when there is disagreement between the diagnosis of negative, inadequate or abnormal, or when the degree of abnormality agreed by the panel would result in a higher-grade management recommendation for the woman. In such cases it is the responsibility of the medical head of the submitting laboratory to take any necessary follow-up action.

#### *11.2.1 Levels of consensus*

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

#### *11.2.2 Identifying missed dyskaryosis*

Consensus agreement for the purposes of identifying missed dyskaryosis (11.3) in either peer group will be determined by assessing whether all valid responses of mild dyskaryosis or worse in the peer group total at least 80%.

#### *11.2.3 Grading consensus*

Consensus agreement on the grading of abnormal slides will be based on all valid opinions for the slide by each peer group. 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. Grading consensus for screeners and checkers is provided for educational feedback.

Only individuals responsible for issuing 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. Quantitative and qualitative feedback on the grading of abnormalities will, however, be provided for personal educational purposes. 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 dyskaryosis. Qualitative feedback will be provided on the identification of infections.

### **11.4 Marking scheme**

The marking scheme is outlined below and presented in detail in Appendices 3 and 4.

#### *11.4.1 All staff*

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

#### *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 for the 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 (0) marks are allocated.
- In the case of ?glandular neoplasia, 2 (two) marks are given for a correct response 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 and 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 peer group in each circulation in rank order and noting the participant code numbers of those with scores below the 2.5 percentile point. In addition, an instance of missed dyskaryosis in a round will mean that the participant has substandard performance.

The first action point occurs when a participant is identified as having persistent substandard performance. This is acknowledged when either of the following occurs in two of the three rounds

- scoring below the 2.5 percentile point
- missed dyskaryosis

If a participant misses dyskaryosis on two or more occasions in one round, or misses dyskaryosis on one or more occasions and falls below the 2.5 percentile point in a single round, performance will not be classified as persistently substandard performance on the basis of this round alone.

The second action point occurs if a participant's performance continues to be substandard or if he or she misses dyskaryosis 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 2.5 percentile point. The three consecutive circulations should be counted on a 'rolling' basis, with the calculation of performance based on the three most recent circulations in which the individual has participated.

## **12. Financial aspects**

Funding of the EQA scheme is included in the budget for regional quality assurance. NHS laboratories therefore pay no subscription for participating in the scheme.

---

# STANDARD OPERATING PROCEDURES

<b>SOP 1</b> Maintenance of protocols and standard operating procedures	17
<b>SOP 2</b> Scheme membership	18
<b>SOP 3</b> Enrolment of new participants	19
<b>SOP 4</b> Obtaining case material	20
<b>SOP 5</b> Initiating a circulation	21
<b>SOP 6</b> Confidentiality	22
<b>SOP 7</b> Receipt and analysis of EQA responses	23
<b>SOP 8</b> Participants' meetings	24
<b>SOP 9</b> Feedback to participants	25
<b>SOP 10</b> Persistent substandard performance	26
<b>SOP 11</b> Communications and complaints	28
<b>SOP 12</b> Oversight	29
<b>SOP 13</b> Managerial accountability	30
<b>SOP 14</b> Finance	31
<b>SOP 15</b> Staffing	32
<b>SOP 16</b> Training	33

## 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 (the 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. This review will identify changes needed to meet the needs of the participants and the actions needed to ensure the continuation of the service. Annual reports will be produced and copies will be submitted to NQAAP, 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 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 before submission of an annual report to the regional EQA scheme organising committee.

Proposals to amend a 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. 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, whether temporary or permanent, who report gynaecological cytopathology samples in the NHSCSP: cytology screeners, biomedical scientists, ABMSPs and pathologists.<sup>6</sup> *Quality Assurance Guidelines for the Cervical Screening Programme*, published in 1996, recommended as a quality standard that all staff screening or reporting cervical cytology participate in EQA (proficiency testing as it was then known) and demonstrate an acceptable level of performance.<sup>11</sup> Staff screening, reporting or training in cervical cytology outside the NHSCSP are ineligible for the EQA scheme.

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

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

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 and comply fully with its conditions and arrangements. Staff working in private laboratories where only private screening is performed are not eligible for the scheme.

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

Signed .....(Regional scheme organiser)

Dated .....

---

## Standard operating procedure 3

### Enrolling 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 this is specifically requested. They are asked to read this document and confirm in writing that they agree to its terms. Once 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 consent in writing to any changes approved by NQAAP to the protocol and SOPs before they are implemented.

Signed .....(Regional scheme organiser)

Dated .....

---

## Standard operating procedure 4

### Obtaining case material

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

All laboratories that are currently performing satisfactorily (ie not at a national action point) in the *External Quality Assessment Scheme for the Evaluation of Papanicolaou Staining in Cervical Cytology*<sup>9</sup> 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. All slides will be panel reviewed to ensure technical adequacy before they are included in the EQA round. The panel must also agree on the classification of the slide. Their 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 approved by the review panel, in line with the *External Quality Assessment Scheme for Gynaecological Cytopathology Handbook for Facilitators*.<sup>5</sup> 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 that includes 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 be given for receipt of responses. To ensure that they receive slides in the chosen technology, it may be necessary for some laboratories to participate in an EQA round provided by another region. If so, the 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 (eg because of prearranged annual leave or illness) may participate in another laboratory in the region. If this is not possible, then one further mutually agreed date for participation will be offered within a month of the completion of the planned circulation. Written records will 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 and through the EQA facilitator. He or she 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; it can then be placed in an appropriately addressed envelope by the facilitator without the facilitator having to examine the contents. The link between participant names and code numbers may be divulged by the EQA facilitator in only two circumstances

1. when writing to a participant who requests a reminder of his or her code number. (Code numbers must not be divulged by telephone.)
2. when writing to the chair of NQAAP in order to investigate a case of persistent substandard performance in the EQA scheme, as set out in SOP 10.

No EQA result may be divulged to any other authority (see Executive Letter EL(98)2).<sup>6</sup> 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 confidence, eg 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, prepare the list of 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. A summary of all results may be presented at the meeting, comparing consensus across the region with known or expected outcomes. Slides may also be available at the meeting for viewing and discussion. 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, and ideally within two weeks. It will compare their performance 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 provided comparing the participant's responses with the consensus. Consensus results will be made 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. He or she posts them to the appropriate participants, along with any general communication that the regional organiser considers necessary. After individual scores have been calculated, the EQA facilitator checks the database to determine whether or not any participants fulfil the criteria for persistent substandard performance. The facilitator may also send a cumulative analysis of the participant's results to allow recognition of trends in performance. Individual and laboratory participation certificates are printed and distributed with the analysis of results.

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 is reached when persistent substandard performance is identified. This happens when either of the following occurs in two out of three consecutive rounds

- Scoring below the 2.5 percentile point.  
After each circulation has been scored, scores are put into rank order. Participant code numbers below the 2.5th centile are recorded.
- Missed dyskaryosis.  
This consists of classifying a slide as negative or inadequate when the consensus opinion is mild dyskaryosis or worse.

If a participant misses dyskaryosis on two or more occasions in one round, or misses dyskaryosis on one or more occasions and falls below the 2.5 percentile point in a single round, performance will not be classified as persistently substandard performance on the basis of this round alone.

Failure to participate in two out of three consecutive circulations (other than on grounds of legitimate long-term absence) should lead to the person ceasing to report cervical cytology. Non-participation will consequently 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 2.5 percentile point) or if he or she misses dyskaryosis 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 be counted as a score below the 2.5 percentile point. The three consecutive circulations should be counted on a 'rolling' basis, with the calculation of performance based on the three most recent circulations. A participant whose performance in both of the two previous 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.

#### **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 and will use the confidential personal code number so that the regional organiser remains unaware of the identity of the addressee. This would follow discussion between the organiser and the facilitator. If the prospective recipient is the regional organiser, however, the facilitator should act on his or her own initiative.

The recipient will be asked to reply to the regional organiser within four weeks, confirming that the letter has been received, offering an explanation for the substandard performance, and suggesting a remedy. The letter should be sent via the EQA facilitator and be identified only by the individual's personal code number.

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 that 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 compromise patient care. The investigation will therefore consider 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 chair of the panel will correspond with the participant. This can initially be done anonymously through the EQA facilitator. These steps should be completed within a maximum of four weeks. 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, copying the letter to the laboratory scientific head for cervical cytology. The letter will be sent from the regional EQA facilitator's office and the confidential personal code number will again be used to keep the identity of its recipient from the regional organiser. The participant will be required to identify him- or herself to the scientific head so that an action plan can 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 responsible for reporting cervical cytology. The regional scheme organiser will expect confirmation within four weeks that this has happened via the regional EQA facilitator, identified only by the participant's personal code number. This confirmation should include a copy of the agreed action plan from the laboratory scientific head or medical head of department as appropriate. 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 in accordance with 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 Specimens*.<sup>13</sup> If a telephone or verbal communication is made, the organiser or facilitator who receives it will make a note summarising its contents, date it, and store it in the file. A questionnaire will be circulated by facilitators to participants on an annual basis to gather 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 can be construed as a complaint, the action taken to remedy it will be recorded, dated and clipped to the original communication in the file. If the regional organiser judges the complaint to be justified and to warrant changes to the scheme's procedures, the preferred sequence for introducing such changes is as follows

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 and 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 NQAAP
6. notification of the revision to facilitators, participants 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.

If satisfaction is still not obtained, the participant can complain directly to the chair of NQAAP.

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 scheme's objectives. 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 must ensure availability of the resources needed for efficient operation of the scheme.

The annual management review must include

- regional reports and 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
- the follow up of previous management reviews.

Comments on how the scheme operates are invited at every participants' meeting. Changes proposed at these meetings will normally be reviewed by the regional organising committee, followed by the EQA subcommittee/steering committee and then NQAAP, as described in SOP 11. Proposals for a replacement scheme organiser should be discussed first at the participants' meeting and, where made by a scheme member, they must be considered. 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 NQAAP. It will include a summary of the national results and include details of any changes proposed by the steering committee – whether planned or in place – in the operation of the scheme. Changes to these SOPs will be reported, as will any changes in the assessment procedure, actual or planned changes in procedures for managing substandard performance in rounds since the last report, and 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 centre is located in each region. Every centre is overseen by a 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 of overseeing the scheme at a national level are included in the budget of the NHSCSP national office. The costs of operating 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 when participating in a scheme must be borne by those laboratories or individuals (eg when locums travel to centres other than those employing them to participate in EQA).

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 Professor 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 .....

---

## REFERENCES

1. *Protocol for a Proficiency Test Scheme in Gynaecological Cytopathology*. London, Department of Health Advisory Committee on the Assurance of Laboratory Standards, 1988.
2. *Recommendations for the Development of Histopathology/Cytopathology External Quality Assessment Schemes*. London, The Royal College of Pathologists Working Group on Histopathology External Assessment Scheme Accreditation, 1998.
3. *Standards for EQA Schemes in Laboratory Medicine*. Feltham, Middx, Clinical Pathology Accreditation (UK) Ltd, 2010.
4. *United Kingdom National External Quality Assessment Schemes, Report and Directory*. Sheffield, UK NEQAS Office, 1988.
5. *EQA Scheme for Gynaecological Cytopathology Handbook for Facilitators*, Version 5. NHS Cancer Screening Programmes, 2011.
6. EL(98)2. *Oversight of Provision of External Quality Assessment Schemes in Histopathology, Cytopathology, Cytogenetics and Molecular Genetics for Pathology Laboratories*. London, Department of Health, 1998.
7. *Standards for the Medical Laboratory (H5)*. Clinical Pathology Accreditation (UK) Ltd, 2007.
8. *Achievable Standards, Benchmarks for Reporting and Criteria for Evaluating Cervical Cytopathology*, 2<sup>nd</sup> edition. NHS Cancer Screening Programmes, 2000 (NHSCSP Publication No 1).
9. *External Quality Assessment Scheme for the Evaluation of Papanicolaou Staining in Cervical Cytology* (NHSCSP Publication No 19). NHS Cancer Screening Programmes, 2004.
10. *Recommended Code of Practice for Laboratories Participating in the UK Cervical Screening Programmes*. London, British Society of Clinical Cytology, 2010
11. *Quality Assurance Guidelines for the Cervical Screening Programme* (NHSCSP Publication No 3). NHS Cervical Screening Programme, 1996.
12. *A First Class Service. Quality in the New NHS*. London, Department of Health, 1998.
13. *The Retention and Storage of Pathological Records and Specimens*, 4<sup>th</sup> edition. London, The Royal College of Pathologists and the Institute of Biomedical Science, 2009.

## 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 with an 'R' the 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 with an 'A' the slides you would refer to a pathologist for reporting on the basis of your opinion. Please look only at slides marked '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

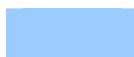



You **must** tick one box and **only one box** in the Result column of the Cytological Pattern section for each slide. Failure to tick a box or ticking more than one box in any column in this section will be penalised as an overcall or undercall as appropriate. Please complete the Additional Features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

Cytological pattern	Result										
	Slide number										
HMR101 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 – missed dyskaryosis

# APPENDIX 4 Scoring matrix for pathologists/ABMSPS

		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	?invasive squamous carcinoma/ ?glandular neoplasia	?glandular neoplasia
R E S P O N S E	Negative	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		Dyskaryotic														
	Inadequate	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0
		Dyskaryotic														
	Borderline changes	0	0	2	4	4	3	3	2	2	2	2	2	2	2	2
	Mild dyskaryosis	0	0	2	3	4	4	4	3	3	2	2	2	2	2	2
	Moderate dyskaryosis	0	0	2	2	3	3	4	4	4	3	3	3	2	2	2
	Severe dyskaryosis	0	0	2	2	2	2	3	3	4	4	4	4	3	3	3
?invasive squamous carcinoma	0	0	2	2	2	2	2	2	3	3	4	3	4	4	3	
?glandular neoplasia	0	0	2	2	2	2	2	2	3	3	3	4	3	4	4	

	Slide correctly interpreted		Slide incorrectly interpreted
	One grade from consensus opinion		Missed dyskaryosis
	More than one grade from consensus opinion		

---

NHS Cancer Screening Programmes  
Fulwood House  
Old Fulwood Road  
Sheffield  
S10 3TH

May 2011