

**EXTERNAL QUALITY ASSESSMENT SCHEME  
FOR GYNAECOLOGICAL CYTOPATHOLOGY**

Protocol and Standard Operating Procedures

**NHSCSP Publication No 15  
January 2003**

First published by:

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ISBN 1 87 1997 94

Further copies of this publication are available from:

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Typeset by Prepress Projects Ltd, Perth ([www.prepress-projects.co.uk](http://www.prepress-projects.co.uk))

Printed by Streamline Offset, Hoddesdon, Herts

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## External Quality Assessment Scheme for Gynaecological Cytopathology

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## ACKNOWLEDGEMENTS

The national office of the NHS Cervical Screening Programme would like to thank all members of the External Quality Assessment (EQA) Working Party for their contribution to the development of this publication. Particular thanks are due to Dr David Slater and his colleagues on the Trent cervical screening quality assurance team for their work in developing and piloting major elements of the scheme.

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## PROTOCOL

The protocol and the standard operating procedures should be read in conjunction with *Standards for EQA Scheme Accreditation*.<sup>1</sup> References to the appropriate paragraphs are indicated by **EQA...**

**1. GENERAL DESCRIPTION OF THE EQA SCHEME (EQA 1A)**

The name of the scheme is the national external quality assessment scheme in gynaecological cytopathology for the NHS Cervical Screening Programme.

**2. SCOPE OF THE SCHEME**

**2.1**

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

**2.2**

This protocol is based on *Recommendations for the Development of Histopathology/Cytopathology External Quality Assessment Schemes* which were developed by the Working Group on Histopathology External Quality Assessment Scheme Accreditation.<sup>2</sup> The recommendations of the working group were endorsed by the Royal College of Pathologists. The protocol has drawn, where appropriate, from the successful experience of the external quality assessment (EQA) scheme in breast screening pathology in use in the NHS Breast Screening Programme (NHSBSP). The protocol replaces the *Protocol for a Proficiency Test Scheme in Gynaecological Cyto-pathology*, which was published by the Department of Health Advisory Committee on the Assurance of Laboratory Standards in November 1988 and will replace any regional schemes based on subsequent draft revised schemes.<sup>3</sup>

**3. SCHEME ORGANISER**

**3.1**

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

**3.2**

Owing to the nature of cervical cytology, in that it does not have the facility to produce multiple specimens and there are large numbers of people wishing to participate, the scheme will have to be operated locally on a regional basis. However, each region will operate to the same national protocol and the national laboratory QA group will act as the scheme's steering committee. The scheme will be organised through the regional quality assurance framework of the NHSCSP, using the infrastructure currently used for the proficiency test.

**3.3**

At a regional level, overall professional responsibility for the EQA scheme will be 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 NHSCSP regional gynaecological cytopathology quality assurance coordinating group. The regional QA group will act as the organising committee for the EQA scheme. The national group includes the regional chairmen and is made up of both medical and scientific staff. The chairman of the national group will act as national scheme organiser.

#### **4. SCHEME SECRETARY**

The secretariat for the national scheme shall be provided by the national office of the NHSCSP. An EQA facilitator will undertake the day to day running of the scheme at a regional level. The facilitator will act as the regional EQA scheme secretary.

##### **4.1**

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 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 professional organiser for the efficient running of the scheme and, for other functions, to the regional quality assurance director who employs him/her.

##### **4.2**

#### **5. NATIONAL OFFICE**

The national office of the NHSCSP is at:

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The Manor House  
260 Ecclesall Road South  
Sheffield  
S11 9PS

Tel: 0114 271 1060

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#### **6. PARTICIPATION**

Participation is mandatory for all individuals reporting gynaecological cytology for the NHSCSP. Names, addresses and code numbers of participants will be recorded by the regional facilitator in the participants' file, which will be held securely at the regional QARC.

#### **7. CIRCULATION OF CASES**

a) There will be 10 slides per circulation with a further two slides included for special educational interest.

b) Initially circulation of slide sets will be once a year. This arrangement will be reviewed in three years' time in the light of technical developments and subject to satisfactory annual reports. Individuals, including staff working as locums, are expected to participate in a minimum of two out of three circulations.

- c) 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.

### 8. SELECTION OF CASES

- a) The slides will be good examples (but not necessarily easy), and will include all eight classifications recognised by the British Society of Clinical Cytology (BSCC), ie negative, inadequate, borderline change, three grades of dyskaryosis, ?invasive squamous carcinoma and ?glandular neoplasia. These classifications are further explained in the *Achievable Standards, Benchmarks for Reporting and Criteria for Evaluating Cervical Cytology*.<sup>4</sup>

The final composition of slide sets for circulation will be left to the facilitators, who will also develop a national protocol and receive statistical advice. This activity will be coordinated through the national office of the NHSCSP, which will ensure that access to facilitators' guidance is controlled. 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.

- b) Adequate clinical information will be provided for each slide, derived from the standard request form (currently the 1990 HMR 101/5).
- c) Guidance published by the Department of Health 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.<sup>5</sup> 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>6</sup>
- d) All NHSCSP laboratories which are currently performing satisfactorily in the technical EQA scheme will be requested to submit smears to the QARC with a consensus opinion from at least a primary screener, checker and cytopathologist. Until such a scheme is fully functioning, laboratories should have either conditional approval or full accreditation with CPA and should not be referred. Histology is only obtained routinely following smears 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. Low grade smears which are included must have been followed by a subsequent smear or a histological diagnosis which is consistent with the original report on the submitted slide. Negative and inadequate slides must have been followed by a negative smear.
- e) A small panel of three or four participants (including a pathologist and a biomedical scientist and a screener and drawn from the regional

laboratory QA group) 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.

- f) The panel should reach an agreed opinion on classification which is consistent with patient history or histology, as appropriate, before a slide can be accepted into the scheme.
- g) The panel members should be drawn from a single region and must not participate in the scheme for which they are selecting slides.
- h) The name of the patient and of the submitting laboratory should be obscured for the purposes of the test. However, the identification should not be effaced from the slide. This should be undertaken by the facilitator, who will also be expected to know where all slides are individually should the need to locate a patient's slide arise 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. The positioning of previous dots should be recorded by the laboratory for medicolegal reasons.
- i) The educational value of the scheme can be enhanced by the addition of up to two cases to add interest. These should be clearly identified as such and should not be used for personal performance analysis.

## **9. THE OPERATION OF THE SCHEME**

### **9.1 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 must not take place until all participants have seen the slides and recorded their results. Senior members of staff should remind participants on each occasion that EQA slides are to be reported 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. A similar approach based on professional honesty has been successful in the NHSBSP and other EQA schemes. EQA facilitators will be available to assist senior members of staff in ensuring that these conditions are adhered to if required. Once all in the laboratory have seen the slides, discussion is encouraged before the slides leave the laboratory.

### **9.2 Routine practice and marking of slides**

All participants should examine cases in a manner appropriate to their routine practice. Laboratories using liquid-based cytology (LBC) will form a separate assessment group for the purposes of EQA. All participants will receive numerical scores and feedback on all areas and not merely those used for performance monitoring.

#### *9.2.1 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 smears, but should sort smears into those which they will report themselves as negative or inadequate and those which they will pass on 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 10 is expected therefore 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 may opt to participate additionally in this type of EQA if they so wish, but their scores will be excluded from the analysis.

### *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 participating in the scheme themselves.

### 9.2.2 *Advanced biomedical scientist practitioner in cervical cytology*

Subsequent to the issue of *Advance Letter (PTB) 2/2001*, it is expected that a number of advanced biomedical scientist practitioners in cervical cytology will be appointed.<sup>7</sup> Their duties will include signing out of abnormal smears 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/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 advanced biomedical scientist practitioners in cervical cytology.

### 9.2.3 *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/inadequate by primary screeners or checkers 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 smears that have been through primary screening. Checkers may wish to participate in this scheme in addition to that for non-medical staff, but their scores must be analysed separately and should not be used for performance assessment but for educational purposes only.

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 screeners and checkers often mark slides; therefore, if this is normal practice, this practice should be followed for EQA scheme purposes too.

An example form to be used to identify EQA slides for EQA for medical staff is included in Appendix 1.

This type of EQA supports the professional work of the cytopathologist as defined by the BSCC Code of Practice,<sup>8</sup> 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, particularly for rescreening negative smears when subsequent abnormalities are found and for 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 all slides, including those that have been marked by screeners and checkers.

## **10. SCORING OF RESPONSES**

### **10.1 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 in 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 responses of all eligible participants in their own peer group, irrespective of whether they received prescreened slides or not. The scoring system will be as follows:

Each individual will be given a confidential, provisional score as they participate in the circulation. This will allow individuals to make comparisons with other participants and with the submitted classification. All participants will receive feedback in three areas:

1. the distinction between negative, inadequate and abnormal
2. grades of abnormality
3. specific infections.

### **10.2 Consensus opinion**

The 'correct' answer will be based on a consensus opinion. Only slides which achieve a regional consensus diagnosis from 80% of participants 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. Immediate feedback can be provided by releasing the 'submitted' opinion on the slides. Consensus agreement between negative, inadequate and abnormal smears will be based on all participants. A similar consensus will apply to infections. Consensus agreement on the grading of dyskaryotic smears will be based only on pathologists' opinions. 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 having responsibility for primary screening or 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.

### **10.3 Assessment of performance**

At the end of the circulation, formal scores can be compared with the consensus. The formal assessment of personal performance differs for the following three groups of participants.

#### *10.3.1 Cytology screeners*

Personal performance will only be formally assessed on the distinction between negative, inadequate and abnormal smears. Quantitative feedback will, however, be provided for personal educational purposes on the grading of abnormalities and identification of infections.

#### *10.3.2 Checkers*

Personal performance will only be formally assessed on the distinction between negative, inadequate and abnormal smears. Quantitative feedback will, however, be provided for personal educational purposes on the grading of abnormalities and the identification of infections.

#### *10.3.3 Pathologists*

Personal performance will be assessed on the distinction between negative, inadequate and abnormal smears and also on the grading of cytological patterns for dyskaryotic smears.

### **10.4 Marking scheme**

The marking scheme is as follows:

#### *10.4.1 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 responses from all participants.

#### *10.4.2 Non-medical staff*

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

#### *10.4.3 Medical staff*

An additional mark is then 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 0 (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 responses are used to assess medical staff grading.

### **10.5 Identification of persistent substandard performance**

Substandard performance can be identified by placing the scores for each circulation into rank order and noting the participant code numbers of those with scores below the 2.5th centile.

The first action point occurs when a participant's scores fall below the 2.5 centile in two out of three successive circulations **or** when a participant makes a clinically serious error, as defined under SOP 10, action point b, on two or more occasions in three successive circulations.

The second action point occurs if a participant's scores continue to fall below the 2.5th centile in two out of three successive circulations after triggering the first action point *or* when a participant makes a clinically serious error on two or more occasions in these circulations. However, in addition, failure to participate in a circulation will also be recorded as a score below the 2.5th centile. If this occurs in two out of three consecutive circulations, then this will be recognised as persistent poor performance and action will be initiated. The three consecutive circulations should be counted on a 'rolling' basis, with calculation of performance always based on the three most recent circulations.

### **11. FINANCIAL ASPECTS**

Funding of the EQA scheme will be included in the budget for regional quality assurance. Subscriptions will therefore not be required for participation in the scheme.

## **STANDARD OPERATING PROCEDURES**



## STANDARD OPERATING PROCEDURE 1

### **Maintenance of standard operating procedures (EQA 1F)**

There will be formal arrangements and meetings between relevant QARC staff and the regional EQA organising committee (the regional gynaecological cytopathology QA coordinating group). The national laboratory quality assurance (QA) group will set, review and revise objectives for the EQA scheme. This group will meet at least twice yearly and will prepare an annual report on the running of the scheme.

Within a region, the scheme should be discussed by the participants and the annual report submitted to the regional QA reference centre.

Each regional scheme organiser will submit the annual report to the national scheme organiser for discussion at the national laboratory QA group meeting. The national organiser will then submit a collated national annual report to the National Quality Assurance Advisory Panel (NQAAP) and the Royal College of Pathologists (RCPath).

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

The scheme organiser will review each SOP annually prior to submission of an annual report to the EQA 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 laboratory QA group.

Signed \_\_\_\_\_ (Scheme organiser)

Dated \_\_\_\_\_

## STANDARD OPERATING PROCEDURE 2

### **Scheme membership (EQA II)**

Participation in EQA is mandatory for all staff working in the NHSCSP who report gynaecological cytopathology smears (cytoscreeners, biomedical scientists and pathologists).<sup>5</sup> *Quality Assurance Guidelines for the Cervical Screening Programme*, published in 1996, recommended as a quality standard that all staff screening or reporting smears should participate in proficiency testing and demonstrate an acceptable performance.<sup>9</sup> This scheme applies to both permanent and temporary staff reporting cervical smears 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.

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

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 will be recognised and action to investigate and, if necessary, 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*,<sup>5</sup> 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 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.<sup>10</sup>

Signed \_\_\_\_\_ (Scheme organiser)

Dated \_\_\_\_\_

## STANDARD OPERATING PROCEDURE 3

### **Enrolment of new participants (EQA 3B)**

Prospective participants will be sent a copy of the scheme's standard operating procedures. They are asked to read this document and confirm in writing that they agree to its terms. Once such confirmation is received by the EQA secretary, a participant code number will be issued and this code will not be known to the scheme organiser.

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

Signed \_\_\_\_\_ (Scheme organiser)

Dated \_\_\_\_\_

## STANDARD OPERATING PROCEDURE 4

### Obtaining case material (EQA 2B, 4G, 4H)

All laboratories which are currently performing satisfactorily in the technical EQA scheme will be requested to submit good examples to the QARC. Until such a scheme is fully functioning, laboratories should have either conditional approval or full accreditation with CPA and should not be referred.

The referral of inadequate slides for reporting (for example, where referral for colposcopy is required when a woman has had three successive inadequate smears) is excluded from the EQA scheme.

There should be an exchange of material between regions to ensure a uniform national standard. This would be organised by the scheme facilitators with different regions being paired for exchange each round.

Signed \_\_\_\_\_ (Scheme organiser)

Dated \_\_\_\_\_

## STANDARD OPERATING PROCEDURE 5

### Initiating a circulation (EQA 3C)

Slide sets will be assembled by the EQA facilitator.

Before each new circulation, explanatory details and response sheets will be sent to each participant. An example of a referral sheet for medical staff, including initial opinions from screeners and checkers, is included in Appendix 1.

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

Signed \_\_\_\_\_ (Scheme organiser)

Dated \_\_\_\_\_

## STANDARD OPERATING PROCEDURE 6

### Confidentiality (EQA 3B, 3F, 3H)

Responses from participants will be identified only by the participant code number.

The code numbers allocated to participants by the EQA facilitator will be held in a locked cabinet and will be accessible only to the EQA facilitator.

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

The link between a participant's name and code number may only be divulged by the EQA facilitator 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 organiser is passed to the scheme secretary with only the relevant code number exposed, such that the communication is placed in an appropriately addressed envelope by the EQA scheme secretary without the secretary having to read the contents of the communication.

The link between participants' names and code numbers may be divulged by the EQA scheme secretary under only two circumstances:

1. in writing to a participant who requests a reminder of his/her code number. Code numbers must not be divulged by telephone
2. in writing to the Chairman of the Histopathology/Cytopathology National Advisory Panel of the Joint Working Group on Quality Assurance 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 *EL(98)2.5*

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

Signed \_\_\_\_\_ (Scheme organiser)

Dated \_\_\_\_\_

## STANDARD OPERATING PROCEDURE 7

### Receipt and analysis of EQA responses (EQA 3D–H)

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

Responses must be given using standard BSCC terminology.

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

A report of the participant's performance will be sent promptly to each participant, comparing the participant's opinions with the submitted classification. The report will include the participant's code number. At the end of the circulation a final report can be given, comparing the participant's score with the consensus.

Records will be held of the time taken to report to participants.

Signed \_\_\_\_\_ (Scheme organiser)

Dated \_\_\_\_\_

## STANDARD OPERATING PROCEDURE 8

### **Participants' meetings (EQA 1H, 2A, 2C, 2D, 3I)**

A regional meeting of participants will be held after each circulation and at least yearly. 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 will be given. Slides will be available for viewing and discussion at the meeting. Nationally, a comparison will be prepared of each region's performance and particularly difficult slides will be reviewed by the national laboratory QA group in order to provide feedback to the regional organisers.

Signed \_\_\_\_\_ (Scheme organiser)

Dated \_\_\_\_\_

## STANDARD OPERATING PROCEDURE 9

### **Feedback to participants (EQA 1H, 2E, 2G, 3D, 3E)**

Immediate feedback is posted to individual participants by the EQA facilitator. This will report an individual's performance compared with the classification at the time of submission of the slide. The envelope will be marked 'personal and confidential'.

Consensus results can only be available when all participants have reported the slides.

Personal reports, together with results of all the participants, are then printed by the EQA secretary, who posts them to the appropriate participants along with any general communication which the organiser deems necessary.

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

Signed \_\_\_\_\_ (Scheme organiser)

Dated \_\_\_\_\_

## STANDARD OPERATING PROCEDURE 10

### **Persistent substandard performance (EQA 1G, 1H, 2E, 2F, 3B)**

#### **Medical staff**

Reaching the first action point by a pathologist will result in a 'Dear Colleague' letter being sent by the organiser to the participant. The letter will be sent from the EQA facilitator's office, using the confidential personal code number, so that the 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 organiser him or herself, then the facilitator should act on their own initiative. The recipient will be asked to write to the organiser, 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 one month, the organiser will write again. If an acknowledgement is still not received within two months the organiser will contact the chairman of the National Quality Assurance Advisory Panel (NQAAP). If the individual concerned is a regional organiser, then the facilitator should use the organiser from a different region to take the matter forward.

When the second action point is reached, the organiser will inform the chairman of the NQAAP, who will convene an appropriate investigation panel. The chairman of the NQAAP has the discretion to coopt a respected local pathologist, such as the local scheme organiser or QA director if this is a pathologist. The organiser will provide the panel chairman 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 which 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. If the correspondence does not satisfy the panel chairman that there is an acceptable explanation and patient care may be at risk, the participant's name will be released to the panel chairman, enabling a direct conversation and possibly a site visit. The panel chairman may choose to delegate this phase of investigation to a local pathologist if the chairman and participant can jointly identify an individual who is acceptable to them both.

These steps should be completed within four weeks at most. If the chairman 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 chairman of the Joint Working Group on Quality Assurance will be informed and will refer the matter to the Professional Performance Committee of the Royal College of Pathologists. 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 facilitator will write to the participant with a copy of the letter going to the laboratory scientific head for cervical cytology. The laboratory scientific head must inform the lead consultant for the cytology service and the medical head of department. If it were the scientific head whose performance was in doubt, the copy letter should then go to the consultant pathologist with responsibility for reporting cervical cytology. The scheme organiser will expect confirmation that this has occurred within 4 weeks and that an action plan has been agreed 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. If there is still no satisfactory response within another 4 weeks, the second action point is reached. The NQAAP chairman will then be informed and will liaise with the regional QA director about further action.

### **Action points**

Action points are defined as follows:

- a) after each circulation has been scored, scores are put into rank order. Participant code numbers below the 2.5th centile are recorded. An action point constitutes being below the 2.5th centile in two out of three consecutive circulations
- b) making a clinically serious error. This constitutes calling negative or inadequate, on two or more occasions in three consecutive circulations, a slide which is graded as moderately or severely dyskaryotic, ?invasive or ?glandular.

Failure to participate in two out of three consecutive circulations allowing for ill-health, maternity leave, etc. 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 chairman of the NQAAP.

When a participant moves regions, whether permanently or on a locum basis, he or she must be required to provide evidence and dates of participation. Any subsequent substandard performance or non-participation which then occurs must be dealt with in the region of current employment.

## External Quality Assessment Scheme for Gynaecological Cytopathology

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

Signed \_\_\_\_\_ (Scheme organiser)

Dated \_\_\_\_\_

## STANDARD OPERATING PROCEDURE 11

### Communications and complaints (EQA 3H, 3I)

All written communication with the EQA facilitator, the regional scheme organiser and the QA team or reference centre relating to EQA will be stored for a period of five years. Where a telephone or verbal communication is made, the organiser or secretary receiving the communication will make a written note summarising the communication and that will be dated and stored in the file.

Complaints from individuals or laboratories about the organisation of the EQA scheme should be made to the organising committee via the EQA facilitator or the EQA professional organiser.

Where the communication may be construed as a complaint, the action taken to remedy the complaint will be recorded and 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. Discussion at the regional participants' meeting.
2. Production of a draft revision to the relevant SOP.
3. Discussion of the revision by the national laboratory QA group.
4. Implementation of the revision pending approval by the Royal College of Pathologists' Steering Committee for EQA in Histopathology/Cytopathology.
5. Notification of the revision to the Royal College of Pathologists' Steering Committee for EQA in Histopathology/Cytopathology.

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 chairman of the Royal College of Pathologists' Steering Committee for EQA in Histopathology/Cytopathology.

Signed \_\_\_\_\_ (Scheme organiser)

Dated \_\_\_\_\_

## STANDARD OPERATING PROCEDURE 12

### **Oversight (EQA 1F, 1G, 1H, 5A)**

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 national laboratory QA group and then by the Royal College of Pathologists' Steering Committee for EQA in Histopathology/Cytopathology and/or NQAAP, as described above. Suggestions for a change of the scheme organiser should be discussed first at this meeting; such suggestions must be considered if made by any scheme member. As far as possible, decisions at the participants' meeting should be made on a democratic basis of those present.

A report will be provided annually to the Royal College of Pathologists' Steering Committee for EQA in Histopathology/Cytopathology and NQAAP on the work of the scheme, with particular emphasis on any changes in how the scheme runs, actual or planned, by the national laboratory QA group. Specifically, any changes in these SOPs will be reported, as will any changes in the assessment procedure, 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.

Signed \_\_\_\_\_ (Scheme organiser)

Dated \_\_\_\_\_

## STANDARD OPERATING PROCEDURE 13

### **Managerial accountability (EQA 1B)**

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 national coordinator of the NHSCSP is accountable to the Department of Health.

Signed \_\_\_\_\_ (Scheme organiser)

Dated \_\_\_\_\_

## STANDARD OPERATING PROCEDURE 14

### **Finance (EQA 1C, 1D)**

The costs of running the scheme and its supervision 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 \_\_\_\_\_ (Scheme organiser)

Dated \_\_\_\_\_

## STANDARD OPERATING PROCEDURE 15

### Accounting (EQA 1C, 1D)

The QARC will keep formal accounts for the EQA scheme in accordance with local requirements.

Signed \_\_\_\_\_ (Scheme organiser)

Dated \_\_\_\_\_

## STANDARD OPERATING PROCEDURE 16

### Staffing (EQA 1C, 1E, GL1A–D)

The national scheme organiser is the chair of the National Laboratory QA Group (currently Dr Paul Cross of Gateshead) and is a function of the post of chairman of the national laboratory QA group, which is held for a period of three years.

The scheme secretary is Mrs Julietta Patnick, national coordinator, NHSCSP, and administration of the scheme 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 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. The arrangements for the appointment of the professional quality assurance lead are as described in *EL(97)67*.<sup>11</sup>

Signed \_\_\_\_\_ (Scheme organiser)

Dated \_\_\_\_\_

## STANDARD OPERATING PROCEDURE 17

### **Training (EQA 1E, GL4B)**

The 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 and will provide training in the operation of the national scheme.

Signed \_\_\_\_\_ (Scheme organiser)

Dated \_\_\_\_\_

# NHS Cervical Screening Programme

## External Quality Assessment Scheme

### Referral of Abnormal Smears 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 or judged 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 as is their normal practice and form their 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 only look at those slides indicated as 'R' by the primary screener. The pathologist will examine the slide as is their normal practice and form their 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										

# NHS Cervical Screening Programme External Quality Assessment Scheme

## Response Sheet

Personal identity code:

Date of test:

Test 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. Only complete the Additional features section as and when appropriate.

### Cytological pattern

### Result

#### Slide number

HMR 101 category	Result code	1	2	3	4	5	6	7	8	9	10
Inadequate	(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
<i>Trichomonas vaginalis</i>										
<i>Candida</i>										
Wart virus										
Herpes virus										
<i>Actinomyces</i> -like organisms										
Other										

## REFERENCES

1. *Standards for EQA Scheme Accreditation*. Sheffield, Clinical Pathology Accreditation (UK) Ltd, 1998.
2. *Recommendations for the Development of Histopathology/Cytopathology External Quality Assessment Schemes*. Working Group on Histopathology External Assessment Scheme Accreditation, 1998.
3. *Protocol for a Proficiency Test Scheme in Gynaecological Cytopathology*. Department of Health Advisory Committee on the Assurance of Laboratory Standards, 1988.
4. *Achievable Standards: Benchmarks for Reporting and Criteria for Evaluating Cervical Cytopathology*. NHS Cancer Screening Programmes, 2000 (NHSCSP Publication No 1, 2nd edn).
5. *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.
6. *Accreditation Handbook (Standard F Evaluation)*. Sheffield, Clinical Pathology Accreditation Ltd, 1999.
7. *AL(PTB) 2/2001: Professional and Technical Staffs B (PTB) Whitley Council: Advanced Biomedical Scientist Practitioner in Cervical Cytology*. Leeds, Department of Health, 2001.
8. *Code of Practice for Cytopathology Laboratories*. London, British Society for Clinical Cytology, 1997.
9. *Quality Assurance Guidelines for the Cervical Screening Programme*. NHS Cervical Screening Programme, 1996 (NHSCSP Publication No 3).
10. *A First Class Service. Quality in the New NHS*. London, Department of Health, 1998.
11. *EL(97)67: Cancer Screening: Quality Assurance and Management*. Leeds, Department of Health, 1997.