



Public Health  
England



# **NHS Cervical Screening Programme**

## **National external quality assessment (EQA) scheme for the preparation and staining of cervical liquid based cytology samples: scheme protocol**

NHSCSP Publication number 19

Second Edition      August 2016

**Public Health England leads the NHS Screening Programmes**

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Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. It does this through world-class science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. PHE is an operationally autonomous executive agency of the Department of Health.

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This updated and amended version of NHSCSP Publication Number 19 reflects the evolution of the External Quality Assessment (EQA) Scheme for the Preparation and Staining of Cervical Liquid Based Cytology Samples since its introduction in to the NHS Cervical Screening Programme (NHSCSP) in 2004. It is updated in recognition of the move to a single operational site and management structure with the preparation of slides from pooled samples and central assessments.

It has been developed in response to the many comments and issues raised during its operation. We are especially grateful to colleagues past and present for providing advice on the methods of making pooled samples and their distribution, and for assistance in revising the definition and categories in the scoring scheme. All have contributed substantially to the extensive revision of this publication.

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## About this document

This document aims to provide guidance on the scheme design, interpretation of results and the general requirements and responsibilities for participation. It also sets out the principles and methodology of operation to ensure a consistent delivery across the nation.

Only the website version of this document is controlled and available for viewing <https://www.gov.uk/government/collections/cervical-screening-professional-guidance>. It should be noted therefore that any printed, downloaded or electronically transmitted file is not a controlled document and it is the responsibility of individuals to ensure that they are accessing the most recent version.

# 1. Introduction

External Quality Assessment (EQA) is one of several tools used by cytopathology laboratories to improve standards in the NHS Cervical Screening Programme (NHSCSP). The fundamental aim of EQA is to maintain and improve the quality of patient care by promoting a high standard of performance and by facilitating personal education. This is facilitated through an independent system of checking laboratory results by an external agency. This system delivers an acceptable degree of reliability and consistency between laboratories by educating, advising, and supporting all participants. EQA complements other Quality Assurance (QA) systems, such as the collection of laboratory statistics and QA site visits.

A consequence of EQA schemes is that instances of persistent substandard performance by an individual or a laboratory may occasionally be revealed, necessitating investigative, and sometimes corrective, action. These instances will probably be a rare occurrence. In such cases, it should be remembered that EQA does not fully replicate the routine laboratory situation and has only limited value as a means of assessing competence in preparation and staining. The results of the EQA scheme, therefore, should not be interpreted or used in isolation and, like clinical audit, should be viewed as part of wider laboratory QA activities and local arrangements for clinical governance.

The Papanicolaou based technical EQA scheme was initially designed to apply to conventional cervical smears and thought to be transferable to liquid based preparations, however, the following issues were encountered:

- the scheme did not match other EQA schemes where a sample is sent to a laboratory for preparation or analysis: instead, a sample is retrieved from laboratory files for assessment
- the scheme did not always allow sufficient time to introduce corrective action before the next assessment is undertaken, if staining was considered substandard
- the SurePath technology used a modified Papanicolaou stain and therefore at a disadvantage when being scored in a scheme designed to assess Papanicolaou staining
- assessor performance was monitored but valid statistical comparisons could not be made due to the difference between regions of both the number of assessors used and the number of assessments each assessor performs



The significant improvements seen in submitted data show that the scheme had achieved its purpose of raising standards in routine cervical cytology staining in England and Wales.

This version of NHSCSP Publication Number 19 has been updated in recognition of the Public Health England QA review and a subsequent move to the preparation of slides from pooled samples and central assessments to evaluate routine staining in cervical cytology.

## 2. Joint Working Group for Quality Assessment in Pathology

The Joint Working Group for Quality Assessment in Pathology (JWG) is a committee of the Royal College of Pathologists, reporting to the Professional Performance Panel. The JWG is responsible for the oversight of all pathology EQA in the United Kingdom (UK), including the approval and registering of schemes, and the setting of policy and maintenance of appropriate professional standards. As part of this remit, the JWG monitors the EQA performance of clinical laboratories in the UK. This is achieved through the use of discipline-specific panels, known as National Quality Assurance Advisory Panels (NQAAP), which report those laboratories that have failed to rectify quality problems to the JWG.

The JWG subsequently works with failing laboratories to improve standards and has the responsibility to handle persistent poor performance to NQAAP (see Figure 1).

The JWG consists of:

- representatives from the pathology professions
- representatives from professional societies
- chairpersons of the NQAAPs
- observers from national government offices
- observers from the United Kingdom Accreditation Service (UKAS)

The JWG is also responsible for the recognition of NQAAPs and steering groups, and for most scheme-related professional matters.

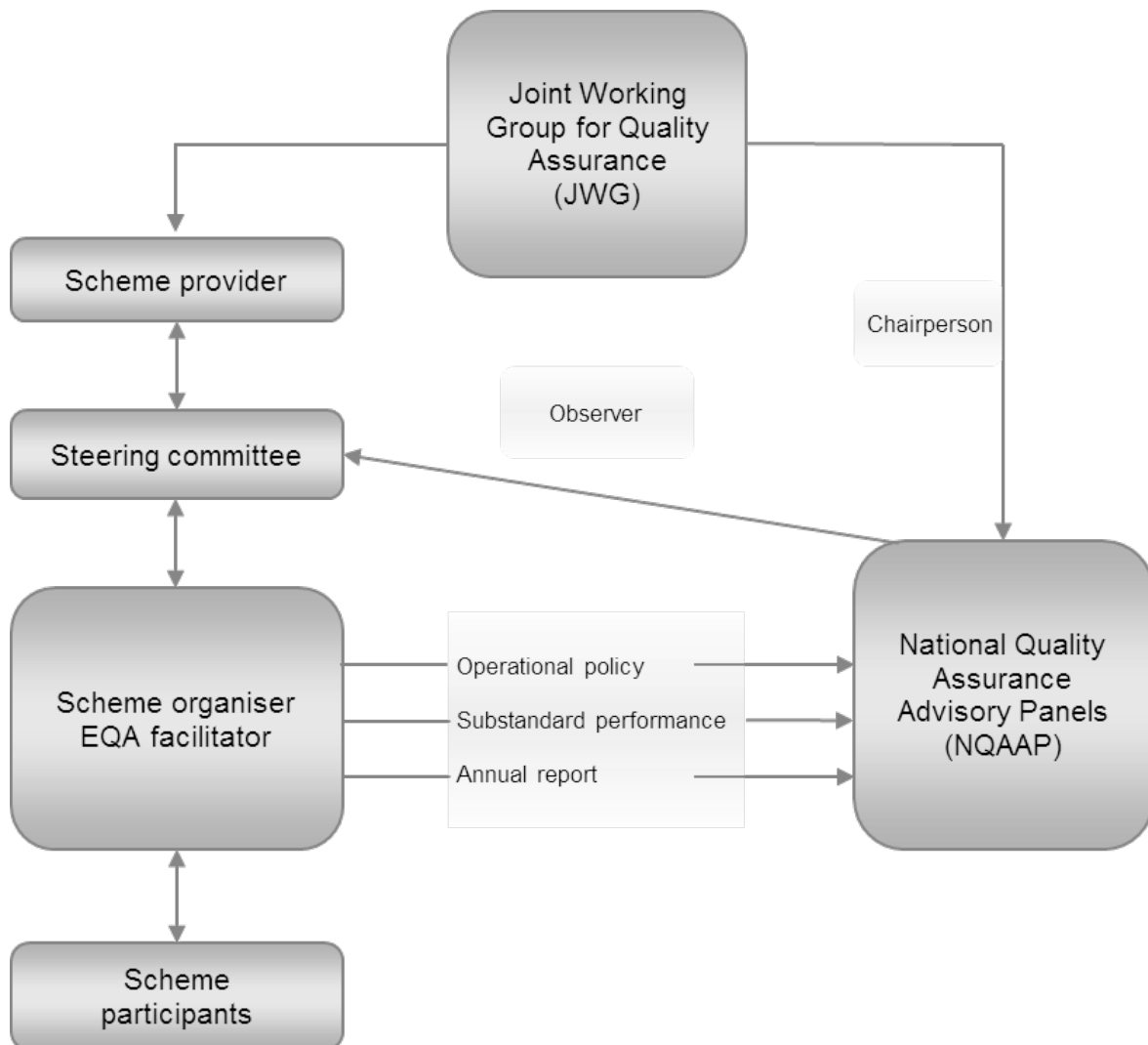


Figure 1: Pathology EQA in the UK

## 3. Scope

The scheme will assess and evaluate stained slides prepared from pooled samples of cervical cells, taking into account the differences in staining methods used, and comment on the overall quality of the preparation. The scheme evaluates the performance of laboratories routinely preparing and staining liquid based cervical cytology samples. The protocol and operating procedures set out in this document apply to the NHS cervical screening laboratories in England and Wales, and laboratories outside the UK which sign up to the EQA agreement.

## 4. Aims

The scheme aims to deliver an acceptable degree of reliability and consistency by educating, advising and supporting all participant laboratories.

A description of the scheme's service and quality objectives is given in the Quality Policy Statement.

## 5. General information

### 5.1 Scheme provider

The provider organisation is a Public Health England executive agency of the Department of Health for its young person and adult screening programmes.

Postal address:

**Young Person & Adult Screening Programmes (YPASPs)**  
**Fulwood House**  
**Old Fulwood Road**  
**Sheffield**  
**S10 3TH**

**Tel: (0114) 201 3064**

**Email: [PHE.screeninghelpdesk@nhs.net](mailto:PHE.screeninghelpdesk@nhs.net)**

**Corporate information: [www.gov.uk/PHE](http://www.gov.uk/PHE)**

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## 5.2 Scheme operation

The scheme is operated by the Screening QA Service (Midlands & East). All general enquiries should be made directly to the National EQA Team.

**National EQA Team**  
**Screening QA Service (Midlands & East)**  
**1st Floor**  
**5 St Philip's Place**  
**Birmingham**  
**B3 2PW**

**Tel: (0121) 214 9130**

**Email: [PHE.TEQA@nhs.net](mailto:PHE.TEQA@nhs.net)**

The telephone line and generic email account are manned on weekdays during normal office hours (09:00 to 17:00). Enquiries are dealt with by staff who have dedicated responsibility for EQA services. Callers should provide identification where this is requested.

# 6. Organisation and management

## 6.1 Scheme locations

Scheme provision is managed across 3 sites: Sheffield, Liverpool and Birmingham.

### 6.1.1 Sheffield

Sheffield provides a general management and administrative function. The scheme's technical manager, who is also the coordinator (laboratories) is employed by Public Health England and based at Fulwood House in Sheffield. The technical manager has shared responsibilities with the quality manager for management systems.

### 6.1.2 Liverpool

The director of screening, Public Health England, is responsible for establishing the organisation's commitment to the quality management system and delegates responsibility for its achievement to the quality manager.

The quality manager (who also provides laboratory support services in cervical cytology education) is subcontracted by Public Health England. The quality manager is based at

Liverpool Clinical Laboratories, part of the Royal Liverpool and Broadgreen University Hospital NHS Trust.

### 6.1.3 Birmingham

The scheme is operated from the Midlands and East Screening Quality Assurance Service, Public Health England. The head of Screening QA Service (Midlands and East) has national responsibility for external quality assessment. A dedicated EQA facilitator manages an administrative team which undertakes the day-to-day organisation and operation of the scheme.

## 6.2 Staffing

### 6.2.1 Scheme organiser

The scheme organiser and deputy scheme organiser roles are subcontracted by Public Health England.

The scheme organiser and his or her deputy:

- is a consultant cytopathologist, a consultant histopathologist with an interest in cervical cytopathology or a consultant biomedical scientist who holds the Advanced Specialist Diploma in Cervical Cytology
- is professionally regulated through their registration body
- is a participant in the Gynaecological Cytopathology Scheme and has experience of selecting and reviewing slides for EQA
- holds a senior post in a laboratory providing gynaecological cytopathology for the NHSCSP
- participates in an appropriate CPD/CME scheme, and fulfils NHSCSP and pre-existing professional body requirements for continuing professional development
- has some knowledge of quality management systems and accreditation requirements

He or she may also be the chair of the EQA steering group.

The scheme organiser and his or her deputy:

- collaborates with the provider organisation in setting annual objectives for the EQA scheme and its strategic direction
- receives advice from the EQA steering group on the practical aspects of scheme design and operation
- is responsible for the oversight of poor performance and liaises with NQAAP in the event of persistent substandard performance

- oversees difficult and sensitive situations associated with laboratory poor performance in the scheme
- approves the scheme's annual report(s) for service users and management
- promotes the value of the EQA scheme and its activities at relevant professional meetings
- promotes and provides advice on the educational elements of the scheme
- responds urgently to any situation arising during the EQA round.

### 6.2.2 Quality manager

The quality manager is responsible for ensuring that all aspects of the quality management system function correctly and are maintained. The quality manager role is subcontracted by Public Health England. The quality manager reports to the scheme organiser for that role. The technical manager deputises for the quality manager in his or her absence. The quality manager is supported by a senior administrator.

### 6.2.3 Technical (scientific) manager

The role of technical manager is undertaken by the coordinator (laboratories) who is employed by and accountable to Public Health England. The technical manager reports to the scheme organiser for that role. He or she is a biomedical scientist who has professional responsibility for ensuring that scheme development complies with programme strategy and ISO/IEC 17043.<sup>3</sup> The technical manager also deputises for the quality manager in his or her absence.

### 6.2.4 EQA facilitator

The national senior external quality assessment (EQA) scheme officer (hereafter termed EQA facilitator) is employed by Public Health England. This individual has the authority to manage the day-to-day operation of the scheme and central assessments in line with published protocols and guidelines. The EQA facilitator reports to the scheme organiser in a professional capacity, and is accountable to the head of screening quality assurance (Midlands and East) who is also their direct line manager. Two administrative assistants who are part of the dedicated national EQA team provide cover for the EQA facilitator in his or her absence. The EQA facilitator has access to technical expertise from within the EQA steering group if this is required.

The role and responsibilities of the EQA facilitator include:

- development and maintenance of local administrative and quality systems in line with published protocols and quality procedures
- liaising with laboratories and assessors to ensure that individuals are given appropriate notice of EQA requirements

- identifying and highlighting actual or potential issues in relation to the scheme's operation and bringing these to the attention of the appropriate manager
- maintaining all aspects of confidentiality and for the safe storage, recording and tracking of samples and slides submitted for use in EQA
- working closely with the local support team to identify areas for development in relation to the online EQA system
- producing accurate reports as requested for management review meetings
- taking action in the event of poor performance as documented in this protocol, and act as the scheme secretary as required.

The EQA facilitator is supported by a local administration team, hereafter termed national EQA team. The national EQA team comprises of staff with defined responsibilities to support the EQA facilitator as well as responsibilities for management and IT/data support. Deputies are identified to cover EQA facilitator duties in his or her absence.

#### 6.2.5 Assessors

Individuals who are nominated to the assessor role must have a minimum of 5 years post qualification experience in the reporting of cervical cytology samples.

The EQA agreement will require nominated assessors to commit to a minimum of 2 assessments per year for a minimum of 2 years (ideally longer) to maintain competence and promote continuity and consistency of assessment. Assessors will receive induction training for the role.

Assessors' scoring will be subject to regular statistical analysis to determine any outliers who may need retraining. The EQA facilitator will provide assessors with feedback on their performance.

Assessors will take turns to lead and direct assessments in line with the published protocol and criteria. A lead assessor will be identified in advance of each assessment.

#### 6.2.6 Trainers

The programme is responsible for providing the initial assessor training and subsequent refresher courses. This will be delivered in NHSCSP approved premises by nominated, qualified staff who have a minimum of 5 years post qualification experience in the reporting of cervical cytology samples and previous experience of carrying out assessments.

The training course provides the assessor cohort an opportunity to meet, reinforces consistency in approach to the assessment criteria, thereby sustaining stakeholder confidence in the scheme

## 6.3 Communications infrastructure

There are established formal and informal channels of communication between the sites via a meetings structure and website systems.

Figure 2 illustrates the EQA relationships within the scheme.

### 6.3.1 EQA management board

An executive team provides a review and governance mechanism for the scheme. This team acts on behalf of, and has direct access to, highest level management, and is responsible for the strategic direction and planning of the national EQA schemes and the management review. Membership includes: national Cervical Screening Programme manager, scheme organiser, deputy scheme organiser, technical manager (scientist), quality manager and head of screening quality assurance (Midlands and East).

### 6.3.2 EQA steering group

The steering group has a supporting and advisory EQA role which includes providing technical advice and assistance on scheme design and operation. Its role, however, does not normally extend to involvement in performance issues unless these are related to the scheme's design and performance monitoring systems.

There may be occasions when an episode of substandard performance, a complaint or appeal requires intervention by the scheme organiser. In such circumstances, the scheme organiser may wish to enlist the help of a biomedical scientist with appropriate technical expertise to provide an independent opinion. It is expected that such expertise will be drawn from the pool of professional and clinical advisors (PCAs) who are contracted to the Screening QA Service.

### 6.3.3 Operational group

The operational group is established to discuss all technical aspects of the scheme including proposals for change, development plans, audits, issues and communications all of which feed into the management review. The national EQA team administers these meetings and members include the quality manager and technical manager; the scheme organiser or deputy organiser may attend and provide advice as necessary.

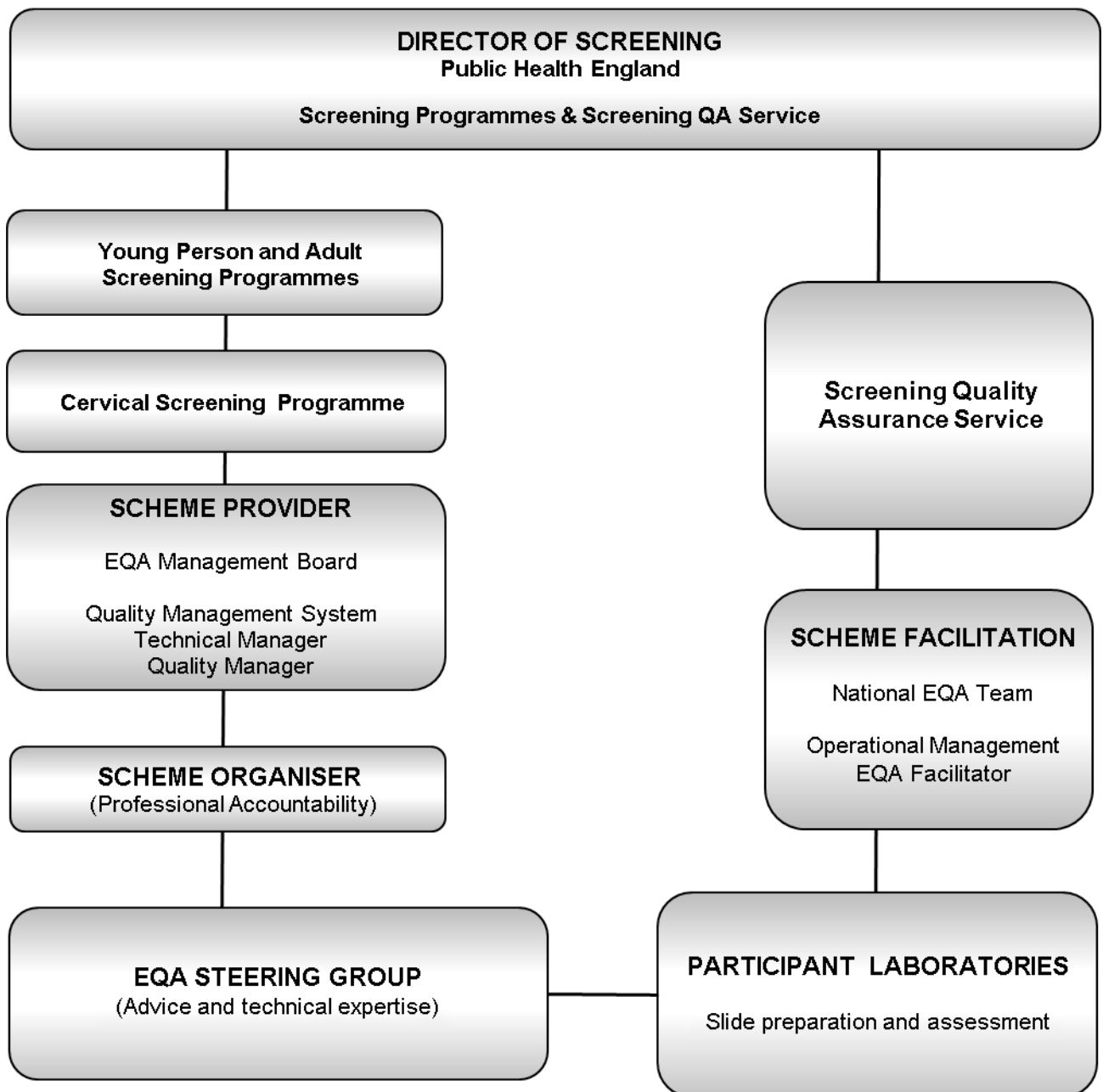


### 6.3.4 Sharepoint repository

This facility provides a secure website link to a repository from which EQA scheme managers can access key documents for the quality management system.

The national EQA team is the first point of contact for general advice and queries about the scheme.

Figure 2: Inter-relationships within the EQA scheme



## 7. EQA agreement

Participation in the Cervical Screening Programme national EQA schemes is mandated in the NHS Public Health Functions Agreement 2015 to 16. Service specification Number 25 outlines the arrangements expected for commissioning the Cervical Screening Programme.

This section of the protocol describes the EQA agreement between Public Health England Screening Quality Assurance Service and NHS cervical screening laboratories and their staff which prepare and/or stain liquid based samples for the NHS Cervical Screening Programme. It is also applicable to laboratories from outside the UK who participate in the scheme.

The general terms and conditions of participation for all parties are documented in the EQA agreement. The EQA agreement is subject to periodic review.

### 7.1 General terms and conditions of participation

Participation in relevant accredited EQA schemes is a prerequisite for laboratories seeking UKAS accreditation against ISO15189:2012<sup>1</sup>.

Laboratories are responsible for notifying the national EQA team of changes in service provision.

Laboratory management is required to monitor and review on-going participation and performance, and to monitor trends in results as appropriate.

Laboratories must confirm their acceptance of all terms and conditions described in the EQA agreement to facilitate enrolment on the scheme. There is no requirement for annual re-enrolment as this is managed through periodic review and renewal of the EQA agreement.

Laboratories are responsible for the safekeeping of EQA material during the round. Damage or breakages must be reported immediately to the EQA facilitator in accordance with local work instructions.

The national EQA team manages the administration of assessment data, generation of result reports and certificates of participation.

## 7.2 Eligibility requirements

### 7.2.1 NHS cervical screening laboratories

All cervical screening laboratories which prepare and/or stain liquid based samples for the NHSCSP must participate in the national scheme and comply fully with all conditions and arrangements.

### 7.2.2 Private laboratories under contract to the NHS

Private laboratories which prepare and/or stain slides under contract to the NHS shall participate in the scheme and comply fully with its conditions and arrangements.

### 7.2.3 Private cervical screening laboratories in the UK

Cervical screening laboratories (not under contract to the NHS) which prepare and stain slides for non-NHSCSP work may wish to subscribe to the scheme. Participation is not mandated for these laboratories.

These laboratories are not eligible to provide the pooled samples or participate in slide assessments since their services are not quality assured by Public Health England.

### 7.2.4 Cervical screening laboratories outside the UK

Subject to operational capability and resources, the scheme is open to laboratories from outside the UK subject to meeting specified terms and conditions of the EQA agreement.

Non-UK laboratories are required to declare the pathway for professional accountability within their employing organisation and regulatory body under the terms and conditions of the EQA agreement. Persistent poor performance will be reported to the relevant regulatory body.

## 7.3 Laboratory enrolment

The head of department (lead clinician) is responsible for ensuring that the laboratory is enrolled as a participant in the scheme.

The laboratory shall identify to the EQA facilitator at least 2 members of staff (termed laboratory leads) as a point of contact for scheme-related matters.

Laboratory leads must accept all terms and conditions described in the EQA agreement to facilitate their enrolment on the scheme. There is no requirement for annual re-enrolment as this is managed through periodic review and renewal of the EQA agreement.

If laboratory leads require clarification of any content or operational matter, then they should contact the EQA facilitator in the first instance.

Laboratories should note that only the website version of the scheme protocol is controlled and this is found at [<https://www.gov.uk/government/collections/cervical-screening-professional-guidance>]. The operational team is responsible for ensuring that laboratories sign up to the website version of the protocol during the enrolment process.

### 7.3.1 Late participation and non-participation in EQA

Laboratories must be aware of the consequences for late and/or non-participation in EQA.

#### 7.3.1.1 Late participation

If slides are received too late to include in an assessment session, then this will be documented as an episode of non-participation. There is a risk that this may lead to a result of poor performance being recorded.

#### 7.3.1.2 Non-participation

A laboratory that fails to participate in 2 consecutive cycles without legitimate reasons will lead to a result of poor performance being recorded. In such circumstances, the EQA facilitator will notify the scheme organiser. The situation will be managed in the same way as poor performance.

A laboratory closure or whole laboratory system conversion are considered legitimate reasons for non-participation, however, all cases will be considered individually and a decision recorded.

## 7.4 Confidentiality

Information disclosure liabilities, responsibilities and procedures are communicated to and followed by all EQA staff, including those employed directly by and /or under contract to Public Health England.

All participant laboratory data is confidential. All electronic data is stored in password protected files or in areas accessible only to EQA scheme staff. Paper based data is stored in a secure, locked cabinet and access is restricted and limited to only EQA scheme staff.

The scheme is confidential under the conditions of participation in EQA schemes determined by the professional bodies through the Joint Working Group for Quality Assurance (JWG). Special arrangements will be employed when local and national action points are triggered.

### 7.4.1 Confidentiality when action points are triggered

Results for any participant laboratory are confidential within the national EQA scheme. The identities of laboratories shall not be communicated except under the terms and conditions of participation.

Anonymity will be broken when:

- sub-standard performance has resulted in actions which require the involvement of the scheme organiser and a QA biomedical scientist if appropriate
- a complaint or an appeal which require the involvement of the scheme organiser and a QA biomedical scientist if appropriate

The names of participant laboratories together with corresponding codes shall be communicated by the EQA facilitator only in the following circumstances:

- when a laboratory is enrolled on the scheme
- when a laboratory lead has requested a reminder of the laboratory code number either in writing or e-mail
- when circumstances dictate that the chair of NQAAP is notified of a laboratory which has reached the second action point. (The chair of NQAAP may request that confidentiality is not broken in these circumstances.)

Laboratory management is required to monitor and review on-going participation and performance in EQA, and to monitor trends in results as appropriate.

Clause 4.10.3 of ISO/IEC 17043:2010 states that: “When an interested party requires the proficiency testing results to be directly provided by the proficiency testing provider, the participants shall be made aware of the arrangement in advance of participation.”

Clause 4.10.4 of ISO/IEC 17043:2010 states that: “In exceptional circumstances, when a regulatory authority requires proficiency testing results to be directly provided to the authority by the proficiency testing provider, the affected participants shall be notified of this action in writing.”

At present, it is considered extremely unlikely that any ‘interested parties’ will require participant laboratory results to be provided directly to them, and nor are there any government regulatory authorities that require participant laboratory results to be provided. If, in the unlikely event that the provider organisation receives a third party request from a regulatory authority requiring EQA results to be provided directly to them, then its source would be investigated and verified. The provider organisation will comply with a valid and verified request and notify the affected participant laboratories of this action in writing within 5 working days.

## 7.5 Sub-contracted services

### 7.5.1 Technical staff

NHSCSP cervical screening laboratories or those under contract to the NHS are expected to be accredited to CPA or ISO standards. Laboratories that are not yet accredited to ISO 15189<sup>2</sup> shall ensure that only qualified and competent staff provide the pooled samples and undertake slide assessment activities for the scheme. Staff are deemed competent on the basis of qualification, experience, on satisfactory performance in the audit of control material and employment by a laboratory which is contracted to provide a cervical screening service to the NHSCSP.

Cervical screening laboratories not under contract to the NHS, including those outside the UK, can participate in the scheme but are not eligible to submit pooled samples or provide staff to undertake slide assessments. Services not under contract to the NHS are not quality assured by Public Health England, or its equivalent in other parts of the UK (Wales, Scotland and Northern Ireland) and are not therefore required to conform to national screening programme standards and guidelines.

### 7.5.2 Laboratory responsibilities

Laboratories are responsible for:

- notifying the national EQA team of the quantity, location, model and serial numbers of all processing/staining machines in routine use, and consumables/supplier(s) upon enrolment to the scheme
- notifying the national EQA team of any changes to equipment, its use and consumables/supplier(s) before the start of each assessment cycle
- notifying the preparation laboratory upon the receipt of pooled samples
- preparing slides on a processor/staining machine as determined by the EQA facilitator
- labelling and dispatching slides in accordance with instructions provided by the EQA facilitator
- taking immediate and appropriate action if any processor and/or staining machine's performance is substandard, and dealing with any ongoing performance issues in accordance with the national protocol
- supporting staff attendance at the annual feedback meeting
- laboratories which nominate staff to take on the assessor role under the terms of the EQA agreement must support an individual's commitment to this activity for a minimum of 2 years/2 assessments per year, in addition to attending the induction training, refresher training and the annual feedback meeting

### 7.5.3 Preparing pooled samples

Two laboratories, one for each current technology, will be required to prepare pooled samples for use in the scheme (hereafter termed preparation laboratories).

Preparation laboratories are required to provide one pooled sample per quarter for each participant laboratory as determined by the EQA facilitator.

The procedure for preparing ThinPrep pooled samples is given at Appendix 1.

The procedure for preparing SurePath pooled samples is given at Appendix 2.

#### 7.5.4 Control slides for audit

The assessments and assessor performance are audited on a rolling basis using control slides. The EQA facilitator will select slides from the previous round to use as controls – 1 high scoring slide, 1 low scoring slide and 1 middle scoring slide and seed them into the assessment set. The audit will commence from the second assessment cycle of the new scheme.

#### 7.6 Professional code of conduct

The scheme relies on professional honesty to ensure that the value and integrity of the scheme is not compromised by behaviour which could potentially influence the validity of results.

Management shall be sensitive in dealing with poor performance and provide support to laboratories underperforming in the scheme. Equally, laboratory leads in underperforming laboratories are expected to avail themselves of the support offered to them.

If, on very rare occasions, it becomes necessary to bring an allegation of malpractice to the attention of the scheme organiser, the procedure for doing so is set out in Appendix 3.

#### 7.7 Financial aspects

The funding of the scheme is included in the budget of the screening division of Public Health England. Assessors are reimbursed for travel expenses to assessment locations.



## 8. Preparation for the EQA round

### 8.1 Planning

The EQA facilitator is responsible for detailed operational planning both directly and through their support team. This includes: consideration of the EQA schedule, number of laboratories and staining machines, liquid based cytology (LBC) technology and the number and rotation of assessors to ensure the statistical validity of assessments. A coding system for individual assessors will be devised to ensure that performance audit can be undertaken in a confidential manner.

Each laboratory shall prepare one slide per circulation which is representative of routine throughput. A laboratory which routinely uses more than one LBC technology will receive 2 vials and prepare and stain a slide on each system.

### 8.2 Production of EQA material

#### 8.2.1 Pooled samples

Prior to the start of the assessment round, the EQA facilitator will liaise with the preparation laboratories to confirm the annual timetable for production and delivery of the pooled samples. The laboratory shall be asked to confirm which technology is in use or if it routinely uses both LBC technologies.

#### 8.2.2 Stained slides

The EQA facilitator will liaise with laboratories to confirm that contact details, type, location and number of machines are up-to-date. The EQA facilitator will also confirm the annual assessment dates and the timetable for the expected receipt of pooled samples and dates by which slides should be stained and dispatched.

#### 8.2.3 Labelling system for test slides

The EQA facilitator will devise a labelling system for use by laboratories. This will allow test slides to be identified by year, round, laboratory and specific machine. The EQA facilitator will devise a labelling system for the control slides.

### 8.3 Supporting information

At the start of each assessment cycle, the EQA facilitator must obtain the following information from laboratories:

- quantity, location, model, serial number of each processor and aining machine(s) in routine use
- coverslip supplier

- slide supplier
- vial supplier (laboratories providing pooled samples only)
- staining schedule
- stain brands
- reagents
- mountant

This information forms part of the assessment and is reviewed alongside assessment results to enable useful feedback to laboratories at the end of the cycle.

#### 8.4 Detection of potentially abnormal material

There may be occasions when abnormal cells are detected in a slide prepared by the laboratory prior to its submission or in a submitted slide during the assessment. Consequently, there is no requirement to take action in these circumstances since the individual samples used will have been reported and cleared for disposal prior to being pooled for EQA purposes,

#### 8.5 Damaged or broken vials

If a laboratory receives a damaged or broken vial which is deemed unsuitable for processing, then the EQA facilitator must be informed immediately so that a replacement can be sent.

#### 8.6 Damaged or broken slides

If a slide is broken or damaged upon receipt and deemed unsuitable for assessment, then the EQA facilitator will contact the submitting laboratory to request a replacement.

#### 8.7 Packaging and transport

EQA materials must be packaged appropriately and transported by Royal Mail special delivery. Packaging for vials must be UN3373 compliant.

## 9. The assessments

There shall be 4 annual assessments per year, from 1 April to 31 March. This is consistent with the frequency of other cellular pathology technical EQA schemes. The quarterly interval will allow time for corrective action and modification to processing and staining protocols between assessments.

### 9.1 Assessment venues

Assessments shall be undertaken at venues with high quality microscopes, multi-headed discussion microscopes, and photomicrography facilities. Internet access and availability of a computer or lap top is also required.

### 9.2 Assessor pool

The EQA facilitator is responsible for maintaining a pool of trained staff to facilitate assessments and provide cover in the event of unexpected absence.

### 9.3 Organising assessments

The EQA facilitator is responsible for organising the schedule of assessments for each technology and notifying the assessors of dates, times and venues. Four trained individuals are required for each assessment panel. A technical lead will be identified from within each panel and it is expected that this person will drive the assessment. A trainee may also attend and participate in the assessment although their scores will not count towards the result.

Contingency plans must be made in terms of the numbers of trained assessors present and back up for facilitation in the event of unexpected absence on the day.

Although an assessment is not a screening exercise, care will be taken to adopt the principles referred to in NHSCSP guidance on laboratory organisation<sup>3</sup> in respect of time spent on microscopy work. The number of slides examined by each panel is not expected to exceed 50 per session.

### 9.4 Compiling the slide sets

Each slide set comprises 30 to 50 slides and is seeded with an additional 3 control slides for the technology being assessed to validate both the assessment process and individual assessors' performance.

The 3 control slides selected from the previous round will include the highest scoring slide, the lowest scoring slide and one midway between those scores.

The slides will be labelled so that assessors are unable to distinguish the control slides from the submitted slides. The placement of the control slides should be different in each successive assessment. The control slides should be assessed in exactly the same way as the submitted slides.

The EQA facilitator is responsible for ensuring the safe transport of slides and accompanying documentation to the assessment sessions.

## 10. Scoring system

The scoring system is restricted to nuclear staining and cytoplasmic staining.

This scheme uses raw scores but restricts the adequate and good categories to slides that score above a set minimum on **both** nuclear and cytoplasmic assessment. By setting different minimum scores for nuclear and cytoplasmic assessment, a controlled automatic weighting of the final score is produced. The scheme also takes into account the balance of nuclear and cytoplasmic scores, rejecting slides that score well on one but poorly on the other.

### 10.1 Scoring for each characteristic

Each slide is rated on 6 characteristics, 3 each for nuclear and cytoplasmic staining. These are detailed below. For each characteristic, a score in the range 1 to 5 may be given. In common with other schemes, points are deducted to a maximum of 5 for detrimental features, rather than being built up from the minimum of 1 for positive features.

A slide may score in the range 3 to 15 on nuclear staining (N) and 3 to 15 on cytoplasmic staining (C), giving a range of total score from 6 to 30.

### 10.2 Overall slide ratings

Slides will be rated as falling in to one of **4** categories:

- good
- acceptable
- marginal
- unacceptable

It is important to note that because the scores are criterion-based, a score of 3 on any individual criterion cannot be interpreted as meaning that the slide is 'average' on that criterion. A slide that scores straight 3s and has a total score of 18 is **not** an average score nor is it an acceptable slide. Awarding marks across a range of 1 to 5 against 4 categories means that a score of 3 cannot be average.

### 10.2.1 Good

To be rated **good**, a slide must:

- score at least 25 overall, and
- score at least 12 on nuclear staining, and
- score at least 11 on cytoplasmic staining

Note that slides scoring 25 or more will, however, not be classed as good in cases where the imbalance between the nuclear and cytoplasmic components is too great. Slides with the following component scores will be reduced to **acceptable** on account of imbalance:

- N15 and C10
- N11 and C14
- N11 and C15
- N10 and C15.

### 10.2.2 Acceptable

To be rated **acceptable**, a slide must:

- score at least 20 overall, and
- score at least 10 on nuclear staining, and
- score at least 9 on cytoplasmic staining

Slides scoring 20 to 24 will not be classed as **acceptable** where the imbalance between the nuclear and cytoplasmic components is too great. Slides with the following component scores will be reduced to **marginal** or **unacceptable** on account of imbalance:

- N9 and C11 or more (marginal)
- N8 or less and C12 or more (unacceptable)
- N12 or more and C8 or less (unacceptable).

### 10.2.3 Marginal

To be rated **marginal** a slide must:

- score at least 18 overall, and
- score at least 9 on nuclear staining, and
- at least 9 on cytoplasmic staining.





### 10.2.4 Unacceptable

Slides rated as unacceptable will be subjected to certain actions as described in section 13.

### 10.2.5 Graphical representation of scores and ratings

The scores and final ratings are represented graphically in Table 1.

**Table 1: Graphical representation of scores and ratings**

Cytoplasmic Staining Raw Score (C)	Unweighted but Restricted													Key
														Overall rating
15	--	--	--	--	--	--	o	-/+	-/+	+	+	+	+	 Good
14	--	--	--	--	--	--	o	-/+	-/+	+	+	+	+	 Acceptable
13	--	--	--	--	--	--	o	-/+	-/+	+	+	+	+	 Marginal
12	--	--	--	--	--	--	o	-/+	-/+	-/+	+	+	+	 Unacceptable
11	--	--	--	--	--	--	o	-/+	-/+	-/+	-/+	+	+	
10	--	--	--	--	--	--	o	-/+	-/+	-/+	-/+	-/+	-/+	
9	--	--	--	--	--	--	o	o	-/+	-/+	-/+	-/+	-/+	
8	--	--	--	--	--	--	--	--	--	--	--	--	--	
7	--	--	--	--	--	--	--	--	--	--	--	--	--	
6	--	--	--	--	--	--	--	--	--	--	--	--	--	
5	--	--	--	--	--	--	--	--	--	--	--	--	--	
4	--	--	--	--	--	--	--	--	--	--	--	--	--	
3	--	--	--	--	--	--	--	--	--	--	--	--	--	
	3	4	5	6	7	8	9	10	11	12	13	14	15	
	Nuclear staining raw score (N)													

## 10.3 Scoring criteria

### 10.3.1 Nuclear stain

#### 10.3.1.1 Differentiation of the haematoxylin

Adequate differentiation is characterised by clear delineation of nuclear components, and lack of residual haematoxylin stain in the cytoplasm of cells.

The score allocated to this criterion indicates the intensity of nuclear staining. It is recognised that this depends upon the degree of differentiation, the time in haematoxylin solution, the type of haematoxylin and/or any combination of these factors.

A low score may result from either very dark staining affecting cytoplasmic colour or conversely very pale nuclear staining.

#### 10.3.1.2 Clarity of chromatin pattern

Chromatin should appear crisp and distinct. It is recognised that a maximum score may only be achievable in a cervical cytology sample with optimal fixation.

#### 10.3.1.3 Haematoxylin colour

Haematoxylin colour should be blue to black.

### 10.3.2 Cytoplasmic stain

#### 10.3.2.1 Colour spectrum

This may be defined as an appropriate range of cytoplasmic colour. The expected colour range will depend on the staining method used.

#### 10.3.2.2 Intensity of cyanophilia

This relates directly to the depth of blue/green colour present.

#### 10.3.2.3 Intensity of eosino/orangeophilia

This relates directly to the depth of pink/orange colour present. Eosinophilia and orangeophilia are combined because it is recognised that some staining methods may not include an orange component, and that orangeophilic cellular material may not always be present in test material.

## 10.4 General (non-scoring) aspects of slide assessment

There are a number of factors which may affect the interpretation of the slide. These include:

- preparation: cellularity, holes, patchiness
- fixation: cellular distortion
- presentation: marked folding or lifting of the cells, air bubbles, scratches on the coverslip, clarity of mountant

Substandard fixation may result in cellular distortion leading to an unusual staining pattern. The cytoplasm of such cells may take up excessive eosin and the nuclear staining with haematoxylin will be less than optimal.

Thick tissue fragments or multi-layered aggregations of cells due to substandard spreading technique may result in improper dye penetration and colours that are not normally expected.

The elements associated with the presentation of material include uneven staining, incomplete dehydration and adequacy of mounting such as air bubbles. The presence of excessive 'cornflake' artefact may deleteriously affect the presentation of material. The reason for its presence is of some dispute but it may be surmised that it often originates from sub-standard laboratory procedures rather than sub-standard fixation.

Translucency is the ability to resolve individual cellular detail within clusters or groups and is influenced by thickness of cervical cytology samples and the 'clearing' properties of the solvents used.

Whilst all of these factors will be noted, they will not influence the overall slide scores.

The scoring criteria for both nuclear and cytoplasmic staining are given at Appendix 4.

## 11. The assessment

### 11.1 Stages of assessment

The assessment of slides will be undertaken in two distinct stages:

- independent examination of cervical cytology samples and subsequent individual scoring to given criteria
- multi-headed microscope group discussion and consensus agreement of a rating score for the slide

All assessments will be made using a colour corrector/blue filter.

The lead assessor will ensure that agreement is reached within the allocated timeframe.

### 11.2 Components assessed

#### 11.2.1 Nuclear staining

Haematoxylin staining of individual nuclei should be:

- clearly visible at low power (x 10 objective), and
- blue to black in colour

At high power (x 40 objective), nuclear chromatin should be:

- clearly demonstrated, and
- appear granular, crisp and distinct

There should be no background staining, apart from cervical mucus, and haematoxylin should not adversely affect the colours of the counterstains.



### 11.2.2 Counterstains

Superficial squamous cells should stain pink; less mature cells should stain blue-green fully keratinised cells should stain orange-yellow or pink depending on the staining method used.

Those colours present should be of equal intensity.

There should be cytoplasmic translucency with a sharp contrast to the nuclear stain.

Polychromasia may be encountered within metaplastic cells where 2 distinct colours are present in the cytoplasm.

### 11.3 Assessing and scoring slides

Assessors are given a pre-populated spreadsheet to complete as illustrated in (Appendix 5).

Assessors view, evaluate and score the slides independently according to the established criteria.

Assessors base their judgement on representative areas of the slide. Areas of poor fixation, air-drying or obscuration should be avoided wherever possible.

A minimum of 4 trained assessors assess each slide, and their scores only must be used for the slide rating.

Each slide carries a maximum 5 marks; marks are deducted for any perceived deficiencies.

Each assessor comments on the technical aspects of overall slide quality. This includes:

- preparation: cellularity, holes, patchiness
- fixation: cellular distortion
- presentation: marked folding or lifting of the cells, air bubbles, scratches on the coverslip, clarity of mountant

Detection of these factors will not influence the overall slide scores although feedback will be given.

### 11.4 Group discussion

At the end of the practical assessment, the lead assessor will identify from the individual mark sheets those slides and raw scores which do not correlate.

The assessors will then convene as a group and review the the outliers on a multi-head microscope and agree an overall score and rating for each slide to produce a final consensus report. This may involve assessors changing their original score for a slide.

The raw scores are used for monitoring individual assessor performance against the final scores. Assessor performance is reviewed after each completed assessment cycle.

## 11.5 Final slide rating

For any slide to be given a final rating of good (rather than acceptable, marginal or unacceptable) at least 3 of the 4 assessors must rate it as good.

For any slide to be given a final rating of acceptable (rather than marginal or unacceptable) at least 3 of the 4 assessors must rate it as acceptable.

## 11.6 Audit of assessments

Regular statistical analysis will be performed on the scores of control slides over different assessments to determine any significant drift from the expected scores which may therefore require corrective action.

## 11.7 Audit of assessor performance

Scores allocated to individual slides should be comparable from assessor to assessor. The score allocated to a slide by an individual in successive assessments should also be comparable. The performance of individual assessors can be monitored by comparison of their individual scores for the same slide between different assessments and between different assessors within the same assessment.

On a national basis, the scores allocated to comparable slides by individual assessors should be similar between assessors in the same assessment and for individual assessors between different assessments.

Assessors are subject to regular performance monitoring of assessments by a statistical analysis of assessor scores and consensus scores. Assessors will be able to make a comparison of their raw scores against those of their peers to facilitate the identification of any training needs.

## 11.8 CPD and CME credits

Assessors are eligible to claim one CPD/CME credit per hour of each assessment session attended.

## 12. Performance analysis

Nationally collected data will be the property of the NHS Cervical Screening Programme.

The EQA facilitator will analyse the results of each assessment and obtain digital photographs of the highest and lowest scoring examples for inclusion in the results package. Details of the highest scoring method will be provided.

The EQA facilitator is responsible for ensuring that the appropriate action is taken when a slide is rated sub-standard.

The EQA facilitator will ensure that the reports and correspondence generated are correctly addressed and distributed.

After each assessment, the EQA facilitator will return the submitted slides to the originating laboratories.

The EQA facilitator is responsible for monitoring assessor performance and will provide appropriate feedback.

### 12.1 Distribution of results

The results package following each assessment will include:

- original submitted slide (unless retained for control purposes)
- a selection of electronic images of different scores taken at the time of the assessment
- a report for each slide assessed
- details of the staining methods used by the highest scoring laboratories in that round
- a graphical illustration of results for the laboratory
- a graph showing laboratory scores in relation to other laboratories
- historical data accumulated during five rounds from when this becomes available

### 12.2 Education and support

Laboratories whose performance is within the marginal category are expected to review their staining procedures.

If a laboratory requires assistance, then this can be obtained via contact with the EQA facilitator in the first instance.

#### 12.2.1 Certificate of participation

A certificate of participation will be issued to each laboratory upon completion of 4 assessment cycles in the EQA round.

## 13. Sub-standard performance

Sub-standard performance is handled in line with guidance from the 'Joint Working Group: Conditions of EQA Scheme Participation'.

The scheme operates the following traffic light system (RAG rating):

- green (no concerns)
- amber (sub-standard performance)
- red (persistent sub-standard performance)
- black (unresolved persistent sub-standard performance)

Criteria for poor performance are proposed by the scheme's EQA steering group in consultation with the EQA management board (NHS Cervical Screening Programme) and approved by the relevant national quality assurance advisory panel.

A slide which obtains an unacceptable score in one round will not be regarded as sub-standard performance at EQA and under the traffic light system will fall in to the green category of "no concerns".

### 13.1 Action points

#### 13.1.1 Local action point (amber)

This is reached when a laboratory's staining is classified as sub-standard performance. This occurs when a laboratory has submitted slides for assessment which are scored as unacceptable in 2 out of 3 rounds of the EQA on a rolling basis.

If the local action point is activated, the EQA facilitator will inform the scheme organiser. The scheme organiser will notify the lead clinician and initiate appropriate advice. The scheme organiser may wish to seek technical advice from a QA biomedical scientist in determining the appropriate response. The scheme organiser will advise the head of screening QA that the local action point has been triggered.

The laboratory will be expected to confirm receipt of formal notification that the local action point has been triggered and provide an explanation. The laboratory will agree a corrective action plan in collaboration with a QA biomedical scientist, if appropriate, and submit this to the scheme organiser.

#### 13.1.2 National action point (red)

This is reached when a laboratory is classified as having persistent sub-standard performance. This occurs when a laboratory has sub-standard performance in 3 out of 4 assessments.

If the national action point is activated, the EQA facilitator will inform the scheme organiser. The scheme organiser will notify the lead clinician, the head of screening QA and the chairman of NQAAP (or equivalent outside the UK within 2 weeks).

The NQAAP chairman should agree in writing any corrective action to be taken and the timescale and responsibility for carrying this out: if appropriate, this letter will be copied to accreditation bodies such as UKAS.

The lead clinician will be expected to contact the scheme organiser (or equivalent in Wales, Scotland and Northern Ireland) for advice with a view to reaching a solution. The scheme organiser may wish to seek technical advice from a QA biomedical scientist in determining the appropriate response. All parties are expected to agree how to manage the situation and keep the EQA facilitator informed.

### 13.1.3 Final action point (black)

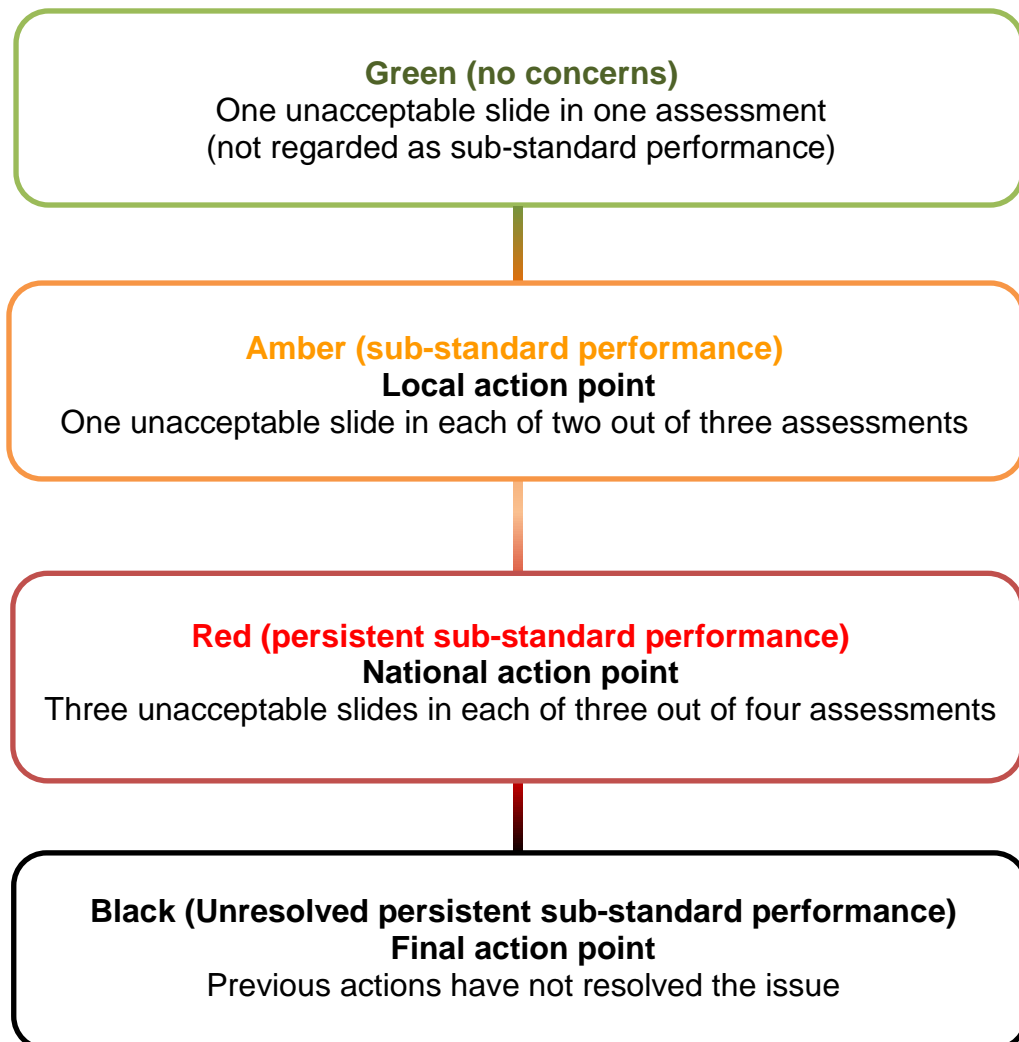
If persistent poor performance remains unresolved, the NQAAP chairman will submit a report to the chairman of the JWG giving details of the problem, its causes and reasons for failure to achieve improvement. The chairman of the JWG will consider the report and, if appropriate, seek specialist advice from a panel of experts from the appropriate professional bodies to advise him/her on this matter.

The chairman of the JWG will be empowered to arrange a site meeting of this panel of experts with the head of the department concerned. If such supportive action fails to resolve the problems and, with the agreement of the panel of experts, the chairman of the JWG will inform the chief executive officer, or nearest equivalent within the organisation of the trust or institution, of the problem, the steps which have been taken to rectify it and if it has been identified, the cause of the problem.

Laboratories outside the UK will be referred to the appropriate regulatory body under the terms of the EQA agreement.

A flow diagram to illustrate the actions following identification of sub-standard performance is illustrated in Figure 4.

Figure 4: Sub-standard performance handling flow diagram



## 14. Communication

### 14.1 Concerns, comments, suggestions and compliments

In this EQA scheme, any concern or comment expressing dissatisfaction about any aspect of its operation or management is construed as a 'complaint'. There are established channels of communication through which participant laboratories can express their concerns or suggest improvements including email, telephone call or letter. In addition, feedback (positive and negative) is actively sought through a national annual survey.

All communications are logged and the appropriate action taken. Records of comments, both positive and negative, are maintained and used for identifying system improvements.

### 14.2 Formal complaints

Formal complaints should be made directly to the EQA facilitator in the first instance. In the event of failure to resolve a complaint to the satisfaction of a participant laboratory, the individual in question can complain directly to the scheme organiser. If satisfaction is still not obtained, the participant can then refer his or her complaint to the chair of NQAAP. The NQAAP decision is final.

The complaints procedure (Appendix 6) describes how to lodge a formal complaint against any aspect of scheme operation or management.

### 14.3 Formal appeals

Formal appeals should be made directly to the EQA facilitator in the first instance. A laboratory may request the reassessment of any slide which it considers to be marked inappropriately. In the event of failure to resolve an appeal to the satisfaction of a participant laboratory, it can complain directly to the scheme organiser. If satisfaction is still not obtained, the participant laboratory can then refer the appeal to the chair of NQAAP. The NQAAP decision is final.

The appeals procedure (Appendix 7) describes how to lodge a formal appeal against a performance evaluation.

## 14.4 Changes to the scheme

Necessary changes to the national scheme may result from a communication, complaint, operational issue or audit finding.

The EQA steering group will make an assessment of the importance of a proposed change and its benefits to the scheme and stakeholders. If the change is accepted then the justification for the change and risks and benefits of making or not making the change will be evaluated. If the change is approved by the EQA management board, then a plan for its implementation will be formalised. The participant laboratories will receive notice of when the change is to be implemented.

## 14.5 Participant feedback forum

An annual EQA feedback meeting provides a forum for discussion of general performance data. The meeting is open to all staff and the participant laboratories are each expected to send at least one member of staff who can then cascade the information to colleagues back at base.

## 14.6 Surveys

Short surveys may be conducted periodically to obtain feedback or views from participant laboratories on actual or proposed scheme activity.

Laboratory leads are encouraged to complete an annual survey, to register their satisfaction with the EQA service and/or provide constructive concerns, comments and/or suggestions for improvement.

## 14.7 Annual report

An annual report will be produced and distributed to participant laboratories, director of screening for Public Health England, screening QA service leads, and other key stakeholders.



## References

1. ISO 17043:2010 Conformity assessment – General requirements for proficiency testing.
2. ISO 15189:2012 Medical Laboratories – Requirements for quality and competence.
3. NHSCSP publication no 14, Laboratory organisation: a guide for laboratories participating in the NHS cervical screening programme.

## Appendix 1: Procedure for laboratories preparing pooled ThinPrep specimens

1. Note and retain the required number of 'in-date' samples (including spares in the event of breakage) in accordance with instructions from the EQA facilitator.
2. Use only samples where the prepared slide was well-stained, clean, mature, good quality and reported as **negative**.
3. Samples selected must have a good endocervical component so that both squamous and glandular elements can be evaluated.
4. Retain (if the intention is to recycle) the original vials or obtain the required number of vials for step 6.
5. Using appropriate personal protective equipment and observing health and safety precautions, mix samples together in a clean measuring cylinder/container which is at least the number of samples required x 20ml in volume.
6. Top up volume to at least the number of samples required x 20ml with PreservCyt and mix gently.
7. Decant 20ml of sample mix into each retained vial.
8. Label each vial appropriately with information provided by the EQA facilitator.
9. Package and send samples quarterly by the due date to laboratories in accordance with instructions from the EQA facilitator.

## Appendix 2: Procedure for laboratories preparing pooled SurePath specimens

1. Note and retain the required number of 'in-date' samples in accordance with instructions from the EQA facilitator.
2. Use only samples where the prepared slide was well-stained, clean, mature, good quality and reported as **negative**.
3. Samples selected must have a good endocervical component so that both squamous and glandular elements can be evaluated.
4. Retain (if the intention is to recycle) the original vials or obtain the required number of vials for step 7.
5. Using appropriate personal protective equipment and observing health and safety precautions, mix samples together in a clean measuring cylinder/container.
6. From the combined deposit, a concentrated cellular deposit of approximately 1.5ml is required and made up to 7ml with SurePath preserving solution.
7. 400µl is then added to the required number of individual vials.
8. Label each vial appropriately with information provided by the EQA facilitator.
9. Package and send test samples quarterly by the due date to laboratories in accordance with instructions from the EQA facilitator.

## Appendix 3: Procedure for investigating alleged malpractice

### 1. Purpose

To establish a procedure for investigating any behaviour witnessed or strongly suspected, whether deliberate or not, which has the potential to compromise the validity of results and consequently damage the integrity of the scheme.

### 2. Scope

This procedure applies to all participant laboratories and EQA staff.

### 3. Policy

The scheme defines malpractice as any behaviour which threatens to compromise the validity of results and its integrity. Formal allegations will be treated seriously and action taken appropriate to the severity of the case under investigation.

### 4. Responsibilities and authorities

All participant laboratory staff and EQA staff have a responsibility for reporting any behaviour which could potentially damage the integrity of the scheme. Any such instances should be notified to the EQA facilitator, or referred to a local laboratory manager for action.

### 5. Procedure

In the first instance, any witnessed or strongly suspected case of malpractice should be notified in writing to the EQA facilitator. The communication will be referred to the scheme organiser for action. A national panel will be convened to conduct an investigation. The chair of the investigation panel will need to correspond with the participant laboratory(ies) involved and in the first instance this will be done through the EQA facilitator. All communications will be logged and held on record.

The **procedure** for participant laboratories which are facing allegations of malpractice is set out below.

The scheme organiser will write to the lead clinician and laboratory lead(s) separately and anonymously via the EQA facilitator within 7 days of receiving notice of the allegation.

The recipients will be asked to respond within 14 days and offer an explanation for the allegation of malpractice. An investigation panel will be convened and the correspondence forwarded to the chair.

If no acknowledgement is forthcoming by 21 days then a reminder will be sent and, if still no reply after a further 7 days, then the scheme organiser will notify the chair of NQAAP.

If malpractice is admitted at this first point then the EQA round of the laboratory concerned will be invalidated and counted as sub-standard performance. The matter will be referred back to the scheme organiser who will provide appropriate feedback and guidance.

## 6 Repeated malpractice

In the unlikely event of an allegation of repeated malpractice, the EQA round of the laboratory concerned will be invalidated and counted as sub-standard performance.

The chair of the JWG on quality assurance will be informed of the further episode and will refer the matter to the Professional Performance Panel of The Royal College of Pathologists and to the medical director of the appropriate trust.

The scheme organiser will notify the NQAAP chair of the position. The NQAAP chair will liaise with the head of screening QA about appropriate further action.

## Appendix 4: Score sheet for the assessment of nuclear and cytoplasmic staining

<b>NUCLEAR STAINING</b>		<b>Marks Deducted</b>	<b>Final Score</b>
<b>A Differentiation</b>			
A1	Optimal intensity of nuclear staining in virtually all nuclei	0	5
A2	Optimal intensity of nuclear staining in the majority of nuclei with acceptable staining in the remainder of nuclei	1	4
A3	Acceptable intensity of nuclear staining without adversely affecting cytoplasmic stains	2	3
A4	Haematoxylin present but under-represented	3	2
A5	Nuclei over-stained and affecting cytoplasm	3	2
A6	Little or no haematoxylin present	4	1
A7	All nuclei heavily over-stained, with haematoxylin in cytoplasm throughout	4	1
<b>B Haematoxylin colour</b>			
B1	Blue/Black colour in virtually all nuclei	0	5
B2	Blue/Black colour in the majority of nuclei	1	4
B3	Purple/Blue colour in the majority of nuclei	2	3
B4	Pink/Red/Green colour in more than 50% of nuclei	3	2
B5	Pink/Red/Green colour in virtually all nuclei	4	1

<b>NUCLEAR STAINING</b>		<b>Marks Deducted</b>	<b>Final Score</b>
<b>C Chromatin</b>			
C1	Crisp and distinct pattern in virtually all nuclei	0	5
C2	Crisp and distinct chromatin pattern in the majority of nuclei	1	4
C3	Chromatin visible, but lacking definition in the minority of nuclei	2	3
C4	Chromatin visible, but lacking definition in the majority of nuclei	3	2
C5	Lack of chromatin definition in all of nuclei	4	1
<b>CYTOPLASMIC STAINING</b>			
<b>D Intensity of Cyanophilia</b>			
D1	Optimal intensity of cytoplasmic staining throughout the slide	0	5
D2	Good intensity of cytoplasmic staining throughout the slide	1	4
D3	Acceptable intensity of cytoplasmic staining throughout the slide	2	3
D4	Inappropriate overall intensity, i.e. <input type="checkbox"/> present, but too pale cyanophilia <input type="checkbox"/> present, but too dark cyanophilia	3	2
D5	Overtly inappropriate intensity, e.g. cyanophilia virtually absent	4	1
<b>E Intensity of Eosino/Orangeophilia</b>			
E1	Optimal intensity of cytoplasmic staining throughout the slide	0	5
E2	Good intensity of cytoplasmic staining throughout the slide	1	4
E3	Acceptable intensity of cytoplasmic staining throughout the slide	2	3
E4	Inappropriate overall intensity, i.e. <input type="checkbox"/> present, but too pale eosino/orangeo <input type="checkbox"/> present, but too dark eosino/orangeo	3	2
E5	Overtly inappropriate intensity, e.g. eosino/orangeo virtually absent	4	1

<b>CYTOPLASMIC STAINING</b>		<b>Marks Deducted</b>	<b>Final Score</b>
<b>F Colour spectrum</b>			
F1	<p>Colour range</p> <p><input type="checkbox"/> All colours relevant to the technology being assessed are equally represented, including subtle shades</p>	0	5
F2	<p>Colour range</p> <p><input type="checkbox"/> All colours relevant to the technology being assessed are equally represented but lack subtle shades</p>	1	4
F3	<p>Colour range</p> <p><input type="checkbox"/> All colours relevant to the technology being assessed are present but one or more is under-represented in the minority of the slide</p>	2	3
F4	<p>Colour range</p> <p><input type="checkbox"/> One or more colours relevant to the technology being assessed are grossly under-represented or are absent in the majority of the slide</p> <p><input type="checkbox"/> Must take account of hormonal status, e.g. a cyanophilic atrophic cervical cytology sample should not result in a poor score</p>	3	2
F5	<p>Colour Range/Lack of Spectrum relevant to the technology used</p> <p><input type="checkbox"/> Cytoplasmic staining is one colour only with no shading or variation</p> <p><input type="checkbox"/> Cytoplasmic staining is two-tone when a monochrome stain is used</p>	4	1



# Appendix 5: Assessor individual score sheet

ASSESSOR ID :

<b>SLIDE CODE NUMBER:</b>																				
---------------------------	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

**ASSESSMENT OF NUCLEAR STAINING**

<b>[A] Differentiation</b>	<b>SCORE</b>																			
<i>Please tick as appropriate:</i> (?under-differentiated)	too dark																			
	too pale																			
<b>Haematoxylin colour</b>	<b>SCORE</b>																			
<b>[C] Chromatin</b>	<b>SCORE</b>																			
<b>SUB TOTAL</b>																				

**ASSESSMENT OF CYTOPLASMIC STAINING**

<b>[D] Intensity of cyanophilia</b>	<b>SCORE</b>																			
<i>Please tick as appropriate</i>	too dark																			
	too pale																			
<b>[E] Intensity of eosinophilia/orangeophilia</b>	<b>SCORE</b>																			
<i>Please tick as appropriate</i>	too dark																			
	too pale																			
<b>[F] Colour range</b>	<b>SCORE</b>																			
<b>SUB TOTAL</b>																				
<b>TOTAL OVERALL SCORE</b>																				

<b>FINAL OVERALL SLIDE RATING:</b> A = acceptable G = Good M = marginal S = substandard																				
---	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

Assessor signature:

Date:

National External Quality Assessment (EQA) Scheme for the Preparation and Staining of Cervical Liquid Based Cytology Samples: Scheme Protocol

Non Scoring Features [please tick [✓]] as appropriate]

SLIDE CODE NUMBER:																				
PREPARATION (cellularity, holes, patchiness)																				
FIXATION (cellular distortion)																				
PRESENTATION (marked folding or lifting of the cells, air bubbles, scratches on the coverslip, clarity of mountant)																				
<b>OVERALL SLIDE QUALITY :</b> <b>A</b> = acceptable <b>G</b> = good <b>M</b> = marginal <b>S</b> = substandard																				

Assessor signature:

Date:

## Appendix 6: Formal complaints procedure

### 1. Purpose

Establish a procedure for dealing with complaints from all stakeholders in the event of dissatisfaction with any aspect of scheme operation or management.

### 2. Scope

This procedure applies to all stakeholders including representatives of participant laboratories and EQA staff.

### 3. Responsibilities and authorities

Representatives of participant laboratories are responsible for following the procedure if making a complaint. EQA staff are responsible for taking appropriate action and offering a solution within the required timeframes.

### 4. Procedure

If a representative of a participant laboratory wishes to make a formal complaint, then he or she should do so by writing to the EQA facilitator.

The EQA facilitator will send a holding response within 3 working days of receiving the complaint.

The complaint is logged together with a summary of the communication and subsequent discussions that may involve other EQA staff including the scheme organiser.

The complainant can expect to receive a response offering a solution within 28 working days.

If the matter is not resolved to the satisfaction of the complainant then the matter will be referred to the scheme organiser. A response will be provided within 28 working days.

If the matter is still not resolved then it will be escalated to the EQA steering group. The EQA steering group decision is final. A final response can be expected within 28 working days.

If the complainant remains dissatisfied with the outcome, or the matter becomes intractable, then they can self-refer the matter directly to NQAAP. The NQAAP decision is final.

## Appendix 7: Formal appeals procedure

### 1. Purpose

Establish a procedure for dealing with participant laboratories in the event of an appeal against an evaluation of its EQA performance.

### 2. Scope

This procedure applies to all participant laboratories.

### 3. Responsibilities and authorities

Representatives of participant laboratories are responsible for making a timely appeal against an evaluation of its EQA performance. EQA staff are responsible for taking appropriate action and offering a solution within the required timeframes.

### 4. Procedure

If a laboratory wishes to appeal against an evaluation of its EQA performance, then the laboratory representative should do so by writing to the EQA Facilitator within 7 working days upon receipt of the report.

The EQA facilitator will send a holding response within 3 working days of receiving the appeal.

The appeal is logged together with a summary of the communication and subsequent discussions that may involve other EQA staff including the original assessment panel and scheme organiser.

The EQA facilitator will convene a different panel to reassess the slide. The appellant can expect to receive a response offering a solution within 28 working days.

If the matter is not resolved to the satisfaction of the appellant then the matter will be referred to the scheme organiser. A further and final assessment panel may be convened at the discretion of the scheme organiser. A response will be provided within 28 working days.

If the matter is still not resolved then it will be escalated to the EQA steering group. The EQA steering group decision is final. A final response can be expected within 28 working days.

If the appellant remains dissatisfied with the outcome, or the matter becomes intractable then they can self-refer the matter directly to NQAAP. The NQAAP decision is final.