

Recommended Code of Practice for Laboratories
Participating in the UK Cervical Screening Programmes
2010

BRITISH SOCIETY FOR CLINICAL CYTOLOGY

Foreword

More than ten years have passed since the last edition of this code of practice. Much has changed in cervical cytopathology, and change continues apace. There is no right time for producing a new edition. Considerations regarding the clinical utility of automated screening and HPV testing in the NHS Cervical Screening Programme (NHSCSP) are on-going and likely to render parts of this third edition out-of date fairly quickly.

For this reason the third edition is being published on the website to enable us to make relevant changes as innovations and new technologies are implemented in the cervical screening programme.

It must be noted that the guidance published in this document is exactly that. Many of the recommendations are based on professional consensus. Where evidence exists it has been referenced. Many of the sections merely draw attention to the relevant NHSCSP, Royal College of Pathologists (RCPATH), Institute of Biomedical Science (IBMS), Clinical Pathology Accreditation (CPA) or other documents or websites. Where possible, suitable links have been inserted to allow for easy web site navigation.

The guidance is aimed at laboratories that work within the relevant cervical screening programme in England, Northern Ireland, Scotland and Wales and recognises the varied service configurations which currently exist, even these may be transitional. Whilst it contains many examples of good practice it is not specifically aimed at laboratories working within the private sector or countries outside the United Kingdom. To ensure that guidance was appropriate to all four screening programmes members of the working party were drawn from each of the four countries. In addition to members of BSCC Council, the IBMS and National Association of Cytologists (NAC) representatives to BSCC Council and the Chair of the NHSCSP National Laboratory QA Group were invited to sit on the working party.

Whilst recognising that individuals working within the profession can be male or female the term “He” will be used throughout this document.

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Cervical Screening Cytopathology

1. Models of service delivery

Almost all cervical screening laboratories in the UK are currently part of larger cellular pathology laboratories within the National Health Service (NHS), where the specific skills of cytology are supported by laboratory and office functions that are common to morphology-based pathology services (i.e. storing and retrieving large numbers of glass microscopy slides and large quantities of descriptive electronic data). A smaller number operate within the private sector.

Cytology laboratories should be large enough to provide a sufficient throughput of work to maintain expertise and quality assurance and facilitate the requirements of commissioners to achieve an adequate turnaround time against service specification. They should also have appropriate links with histopathology, gynaecology and other clinical departments to allow for invasive cancer audits, multi disciplinary team meetings (MDTs), and other relevant fora such as local working groups. The BSCC supports the recommendation of the Cancer Reform Strategy

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_081006 that the suitable minimum workload to achieve this currently is 35,000 samples per annum.

The BSCC expects that there will be a process of evolution to achieve this new configuration, but in the interim recognises that different service models exist.

Whatever the size of laboratory, and whether or not it is allocated its own budget, the cytology section should be led by a named medically qualified consultant (subsequently referred to as a “Medical Consultant”) who works in that discipline on a regular basis. In addition there should be a named deputy medical consultant and a lead biomedical scientist (BMS) who is responsible for the day to day management of the department and has responsibility for oversight of non medical staff. There should be an accountability structure in place and all staff must have roles and responsibilities clearly defined in their job description.

Local services must ensure that there is adequate and appropriate consultant cover, if necessary, from another site or through a network arrangement.

All screening and reporting for the NHSCSP must take place in a CPA accredited laboratory

<http://www.cpa-uk.co.uk/> It is not appropriate for slides to be screened in a non-laboratory setting and screening and reporting from home must not be carried out. It is expected that consultants who work in more than one hospital will report cervical cytology at the cervical cytology laboratory, and not at any other base.

1.1 Networks

Networked pathology departments may vary in their complexity and formality of arrangement.

A number of services have formed informal networks, with cytology laboratories organised in ‘hub and spoke’ arrangement: all specimens are processed at the hub whilst screening takes place at several sites.

All laboratories in this case will work independently and submit separate KC61 or equivalent data. There will be the requirement to develop clear service level agreements detailing the relevant responsibilities between all laboratories and their host organisations.

For a formally managed network to be considered as one department, and thus submit a single KC61, all sites within the network that perform cervical cytology screening must adhere to the same policies and protocols and have a single clinical lead. CPA has clear guidance on this, which can be found at their website:- <http://www.cpa-uk.co.uk/support/index.htm>

There must be:

- A single annual management review
- Regular meetings between management and the staff involved in all branches of the network
- Assured equity of access to pathology data and interpretive advice for all users
- A single user manual which may contain separate sections for its constituent units
- A common format for requesting investigations and reporting results
- A common format for written procedures (SOP`s) across the network

Medical consultant cover must satisfy the following criteria:

- There must be a written statement of the sessional input to meet service needs
- There must be on site laboratory attendance, as required to meet the needs of the service, including the 14 day turnaround time target.

Meeting these requirements is greatly facilitated by the use of a single computer platform and sample numbering system. A single management structure, employing Trust and consultant lead are necessary to give the service a single strategic direction. It is necessary to ensure excellent communication across the network to facilitate a unified service.

Where there is movement of personnel or workload around the network there must be an effective tracking system so that specimens can be easily traced. Transportation of specimens between networked laboratories must comply with the guidance laid down in section 15 of this document and must adhere to NHS Code of Practice for Information security management.

2. Staffing Recommendations

2.1 Medical Consultants

Participation in the provision of cytopathology services is a matter for local management, under the direction of the head of cellular pathology services. Although there are a few consultant cytopathologists [medically qualified cellular pathologists practicing exclusively in cytopathology], most consultant cellular pathologists also practice in histopathology and autopsy pathology.

The BSCC supports the RCPATH recommendation that all pathologists should participate in continuing professional development (CPD) relevant to their clinical practice.

All cervical cytology samples that have been identified as abnormal or possibly abnormal must be examined by a medical consultant or a consultant BMS. The medical consultant or consultant BMS should have experience in screening unmarked slides, especially for the rescreening of negative samples reported as negative when subsequent abnormalities are found and for the review of slides as part of clinical audit.

To maintain a medical consultant's diagnostic skill in cervical cytopathology their minimum yearly workload must not be less than one programmed activity in cervical cytology which equates to 500 cases. Further samples will be reviewed, for example, for audit and correlation purposes and these in addition will result in the individual examining more than 750 cases per annum. (see section 6.1).

Appropriate Programmed Activities (PAs) should also be allocated for laboratory and screening programme management, audit, teaching, continuing medical education and research. All consultant pathologists participating in the cervical screening programmes must participate in a recognised cervical cytopathology external quality assurance (EQA) scheme. If there is an absence from work for a period exceeding six months then the individual should undertake a short period of retraining. This could take the form of in house training sets or attendance at a formal update course at an approved cytology training centre.

The laboratory service, whether stand alone or networked, should be supervised by a medical consultant and he, or a deputy, should normally be in attendance every working day. (See section 2.2.1). In a network there must be sufficient consultant supervision at all sites (see 1.1)

The medical consultant:

- is responsible for the quality of the work including the establishment of monitoring procedures and maintenance of efficient working practices.
- should participate in regular MDT / CPC meetings (see section 13) as described by local policy
- should review concurrent and subsequent histological biopsies as part of mandated invasive and local audit procedures.

- has an important role as an intermediary between the laboratory and other clinical staff including general practitioners. He will spend time in clinical consultations, with individual clinicians and at clinico-pathological conferences or MDT meetings. As well as diagnostic opinions, advice may be sought on appropriate cytological investigations, suggestions for further investigations and management of patients.
- has a responsibility for educating trainee medical and non-medical staff that spend time in cervical cytopathology as part of their training in cellular pathology. Such trainees must not be regarded as part of the permanent staffing. He may also contribute to postgraduate education of primary care and hospital staff.
- is in a position to initiate and assess the potential contribution of the cytopathology service to clinical, research, or screening projects so that resources are used to the best advantage.

A medical consultant working in the cervical screening programmes must have considerable experience and understanding of the multidisciplinary and multi-institutional nature of the programme, and have appropriate managerial skills. As such additional qualifications in management are desirable.

2.1.2 Appointment of Medically Qualified Consultant Pathologists

All doctors in an honorary, fixed-term or substantive NHS consultant pathologist post will have had their name entered on the Specialist Register of the General Medical Council. Doctors who have satisfactorily completed an approved specialist training programme in the UK will have obtained specialist registration by submission of a Certificate of Completion of Training (CCT). Doctors who have trained outside the UK will have obtained specialist registration by demonstration of equivalent training, qualifications and experience through Article 14. Further information and useful links are to be found on the RCPATH web site at <http://www.rcpath.org/index.asp?PageID=146>.

Some applicants for consultant pathologist posts who have qualified and trained outside the UK will have achieved inclusion on the Specialist Register of the GMC without any training in the NHSCSP. RCPATH guidance is that this should be assessed at interview and if the applicant is appointed to a post involving practice in the NHSCSP, local training and supervision must be arranged.

<http://www.rcpath.org/index.asp?PageID=965>

FRCPATH training is specific to cervical cytology collection and preparation systems – conventional, ThinPrep or SurePath. Holders of the FRCPATH who wish to practice using a system other than that in which they were trained must undertake appropriate conversion training. Information on conversion training is available from the cytology training centres.

2.1.3 Trainee medical staff in cellular pathology

Trainee medical staff will have clearly identified periods as defined by the RCPATH Curriculum for Histopathology and Related Specialties 2007

http://www.rcpath.org/resources/pdf/g051_histocurriculum_aug08.pdf

in which to gain experience of cervical cytopathology, management of a cervical cytopathology laboratory, and management of a local cervical cytology screening programme.

Those trainees in the UK wishing to specialise in cytopathology may follow the specialist curriculum for post FRCPath training in cytopathology. This is assessed by portfolio and leads to a recognised sub-specialist qualification in cytopathology. It is described in the RCPATH Curriculum for Histopathology and Related Specialties 2007.

2.2 Biomedical Scientists (BMS)

2.2.1 Consultant Biomedical Scientists (A4C Band 8a – 8d)

For the purpose of this document consultant BMS staff are those who hold the Advanced Specialist Diploma in Cervical Cytopathology, run by a conjoint Board of the IBMS and RCPATH. The BSCC recognises that post holders may have a variety of different job titles.

Consultant biomedical scientists are able to report abnormal cervical cytology samples and make recommendations on appropriate patient management. In order to maintain diagnostic skills in cervical cytopathology consultant BMSs must undertake the equivalent of one programmed activity in cervical cytology which would equate to at least 500 cases. Further samples will be reviewed, for example, for audit and correlation purposes and these in addition will result in the individual examining more than 750 cases per annum. (see section 6.1).

Appropriate time should also be allocated for laboratory and screening programme management, audit, teaching, continuing medical education and research as appropriate.

All consultant BMSs participating in the cervical screening programmes must;

- Participate in a recognised cervical cytopathology EQA scheme
- Be HPC registered and undertaking and recording appropriate CPD activities
- Undertake three days of update training every three years
- Undertake four days of in-house update training per annum (see section 7.6)
- Undertake the relevant formal documented in house training if returning to cervical cytology after a period of absence of more than three months. If the absence exceeds six months then external training may be required.

Consultant BMSs are able to undertake many tasks undertaken by consultant medical staff, as outlined below:

- participate in regular MDT meetings / CPC sessions (section 13, as described by local policy)

should review concurrent and subsequent samples as part of mandated invasive and local audit procedures.

- have an important role as an intermediary between the laboratory and other clinical staff including general practitioners. As well as diagnostic opinions, advice may be sought on appropriate cytological investigations, suggestions for further investigations and management of patients.
- have a role in teaching junior medical staff who will spend time in cervical cytopathology as part of their training in histopathology. He also has a commitment to participate in the training of non-medical staff, postgraduate education of hospital medical staff and staff in primary care.
- is in a position to initiate and assess the potential contribution of the cervical cytopathology service to clinical, research, or screening projects so that resources are used to the best advantage.

Laboratories that provide a cervical screening service and employ a consultant BMS require the following staffing arrangements:

In a stand alone laboratory:

A minimum of two medical consultants, who actively practice cervical cytology, in addition to the consultant BMS.

In laboratories that form part of a network:

A minimum of one medical consultant who is actively practicing cervical cytology working on site with the consultant BMS. Where network arrangements are in place there should be written service level agreements between the laboratories specifying the cover required and provided. These should also make clear which Trust has medico-legal responsibility. Laboratories forming the cytology network must have common reporting and management protocols to facilitate cover arrangements and medical consultants and consultant BMSs who work as part of a cytology network should meet at least quarterly to establish a common understanding of competency and working practices.

The BSCC acknowledge that, due to outside commitments, sickness or leave, it may not be possible for the medical consultants to be present in the laboratory every working day. This should not prevent consultant biomedical scientists from reporting abnormal cases in these limited circumstances, but such absence should not be routine and should be time limited. Consultant medical cover arrangements must be made when these absences extend over several days.

Training & Education

Consultant BMS staff MUST hold the Advanced Specialist Diploma in Cervical Cytology that is run and administered by a conjoint Board of the IBMS and the RCPATH. The diploma is open to individuals who are;

- A Fellow of the Institute of Biomedical Science

- Hold current HPC registration
- In possession of the Institute's Higher Specialist Diploma in cytology or equivalent (e.g. Fellowship examination or relevant MSc)
- Have more than five years full-time equivalent post registration experience in cervical cytology particularly at the "checking" level
- In possession of the NHSCSP Certificate in Cervical Cytology (or preceding IBMS/BSCC Certificates of Competence in Cytology Screening)
- Completed a NHSCSP Course in Advanced Practice.
- Have completed a portfolio of training as laid down by the Conjoint Board

There should be a single named consultant pathologist trainer who has overall responsibility for guiding and monitoring the progress of the biomedical scientist in training.

Further details on the examination are available from the IBMS; <http://www.ibms.org> or email: mail@ibms.org

2.2.2 Laboratory Manager / Scientific Head (A4C Bands 8a – 8b, depending on role)

The laboratory manager or scientific head of the department will carry out any number of tasks depending on the size and complexity of the individual department and its staffing structure. It is accepted that not all scientific heads will continue to evaluate cervical samples. The laboratory manager/scientific head will adopt a key supporting role by assuming responsibility for technical and laboratory based aspects of the work. They will work collaboratively with the medical consultant and HBPC to monitor and maintain a high quality service.

A range of duties is listed on page 5 of NHSCSP document number 12.

<http://www.cancerscreening.nhs.uk/cervical/publications/nhscsp12.pdf> The BSCC supports these recommendations and where the Scientific Head participates in examining cervical samples we would emphasize that they must:

- Examine a minimum of 750 / 3000 cases per annum depending on the specific role undertaken (see sections 5.1 / 4.1)
- Participate in the relevant regional EQA scheme
- Undertake three days of update training every three years
- Be HPC registered and undertaking and recording appropriate CPD activities
- Undertake four days of in-house training per annum (see section 7.6)
- Undertake relevant formal documented in house training if returning to cervical cytology after a period of absence of more than three months. . If the absence exceeds six months then external training may be required.

2.2.3 Hospital Based Programme Co-ordinator (HBPC)

The role of HBPC was introduced into English laboratories in 1997, when it was originally described in NHSCSP document no 7. The original role has expanded with the publication of subsequent NHSCSP documents and NHSCSP number 7 is no longer available nor relevant. The role of HBPC must be undertaken by a person with a thorough understanding of the cervical screening programme. This could be a consultant pathologist or BMS, other individuals such as cytology laboratory managers, or those from a clinical background such as gynaecologists and nurse colposcopists. Whoever is in post they should be sufficiently experienced and knowledgeable to be comfortable with, and if required contribute to, Board level discussions and be directly accountable to a named highly placed individual within the organisation who is independent of the pathology directorate.

Whatever the background of the HBPC, sufficient time should be allocated within their job plan. The time necessary should not be underestimated and will vary depending upon the size and complexity of the organisation and support staff available. The BSCC suggest that for most HBPCs a minimum of one session per histology laboratory or colposcopy unit should be allocated. For those working within networks, or across multiple sites and colposcopy units more time must be made available. 0.2 wte secretarial support per hospital should be made available to support the work of the HBPC.

The role of the HBPC is complex and many faceted. He should have overall responsibility for the following responsibilities but may delegate certain tasks to appropriately experienced and qualified staff. This is not an exhaustive list and each Trust may add to it according to local arrangements:

- To oversee the coordination, quality and effectiveness of the cervical screening programme linked to the laboratory.
- To be responsible for coordinating the quality and clinical information services for women who are diagnosed and/or treated within the Trust.
- To act as a link for screening commissioners, PCT leads, programme leads and regional quality assurance teams.
- To ensure that all new cases of invasive cervical cancer are audited in accordance with NHSCSP no 28. <http://www.cancerscreening.nhs.uk/cervical/publications/nhscsp28.html>
- To be a member of the incident panel if a cervical screening “serious untoward incident” is identified within the Trust
- Be directly accountable to a named highly placed individual within the organisation who is independent of the pathology directorate
- To ensure that the cytology laboratory and/or colposcopy department performs in accordance with NHSCSP guidelines.
- To ensure there is timely collection of national data in colposcopy and cytology
- In conjunction with the lead colposcopist to ensure that colposcopy waiting times and Did Not Attend (DNA) rates are monitored in relation to current NHSCSP guidelines.
- To ensure that cervical screening turnaround times are monitored in relation to current NHSCSP guidelines.

- To ensure that an effective laboratory failsafe system is in place (NHSCSP no 21)
<http://www.cancerscreening.nhs.uk/cervical/publications/nhscsp21.html>

The role of the HBPC does not operate in Wales as it does in England. Many functions of the HBPC are carried out by the Regional Programme Co-ordinators who report directly to the Director of Cervical Screening Wales.

2.2.4 Quality Manager

Whilst the BSCC do not wish to be prescriptive about the potential role of quality managers, departments should nominate a named individual(s) in line with CPA requirements listed in section A7 of the Standards for Medical Laboratories. <http://www.cpa-uk.co.uk/>

2.2.5 Supervisory BMS Staff (Agenda for Change Band 7 & 8)

A suitable ratio of supervisory BMS (A4C bands 7 - 8) to BMS bands 5 & 6, trainee BMS, cytology screeners and medical laboratory assistants (MLAs) is necessary to provide satisfactory supervision for the checking of cervical samples, training, service development and quality control. A senior member of the BMS staff (A4C band 7/8) may supervise up to four other members of staff.

As well as the screening of cervical samples, supervisory BMS should have time for the discussion of abnormal and equivocal cases with staff, training staff, monitoring preparatory techniques, internal audits, matters pertaining to health & safety and other duties such as monitoring the fail-safe mechanism. The BSCC supports NHSCSP guidance document 12

<http://www.cancerscreening.nhs.uk/cervical/publications/nhscsp12.pdf> that supervisory staff must see a minimum of 750 / 3000 cases per annum depending on the specific role they are undertaking (see sections 4.1 / 5.1)

They must also:

- Participate in the relevant regional EQA scheme
- Undertake three days of update training every three years
- Be HPC registered and undertaking and recording appropriate CPD activities
- Undertake four days of in-house training per annum (see section 7.6)
- undertake the relevant formal documented in house training if returning to cervical cytology after a period of absence of more than three months. . If the absence exceeds six months then external training maybe required.

2.2.6 Training Officers (City & Guilds assessors)

Training officers will normally be banded as at least grade 7 under Agenda for Change. They are responsible for the training of all non medical trainees including both trainee BMS and cytology screeners.

Where laboratories have current cytology trainees a major role of the training officer will be to act as a **C**ity & **G**uilds assessor. All training officers with a trainee must be registered with their local cytology

training centre and more importantly with the national centre. Information on this is available through local cytology training centres or the City & Guilds website: <http://www.cityandguilds.com/18719.html> In addition to training of trainees, training officers would usually be responsible for co-ordinating in house and formal education of all staff members. This would include liaising with local cytology training centres to ensure staff can access mandatory three year updates and ensuring that there is one day per quarter given over to internal education. This might be in the form of slide meetings, lectures or other internal CPD activities.

As above the BSCC supports NHSCSP guidance in NHSCSP document 12 that training officers must screen a minimum of 3000 or 750 cases depending on the specific role they are undertaking. (see sections 4.1 / 5.1) They must also:

- Participate in the relevant regional EQA scheme
- Undertake three days of update training every three years
- Be HPC registered and undertaking and recording appropriate CPD activities
- Undertake four days of in-house training per annum (see section 7.6)
- Undertake relevant formal documented in house training if returning to cervical cytology after a period of absence of more than three months. If the absence exceeds six months then external training maybe required.

Training & Education

There is no recognised formal training for training officers although those acting as C&G assessors will receive training from their local training centre.

The BSCC recommend that those appointed to this position should **have** a minimum of five years post qualification experience in cervical cytology.

Training officers must obviously participate in a recognised CPD scheme and satisfy other NHSCSP criteria as listed above.

2.2.7 BMS 1 staff (Agenda for Change Grades 5 & 6)

BMS 1 staff can participate in the primary and double and rapid screening of cervical samples. They may sign out cases which they deem to be negative or inadequate. All other cases **MUST** be passed on to a checker, consultant BMS or pathologist.

A range of duties is listed on page three of NHSCSP document number 12

<http://www.cancerscreening.nhs.uk/cervical/publications/nhscsp12.pdf> The BSCC supports these recommendations and would emphasize the following.

A BMS 1 must:

- be HPC registered and hold the C&G Diploma or equivalent
- screen a minimum of 3000 cases per annum (see section 4.1)
- participate in the relevant regional EQA scheme
- undertake three days of update training every three years
- Be HPC registered and undertaking and recording appropriate CPD activities

- Undertake four days of in-house training per annum (see section 7.6)
- Undertake the relevant formal documented in house training if returning to cervical cytology after a period of absence of more than three months. If the absence exceeds six months then external training maybe required.

Training & Education

Where BMS staff intend to participate in cervical screening, training will be similar to the training for cytology screeners and will be aimed at successful completion of the City & Guilds Diploma in Cervical Cytology. This qualification is mandatory for all new staff reporting samples within the Screening Programmes within the UK. http://www.cityandguilds.com/documents/ind_healthsocial_health/3166-01-13-hb-v02.pdf

The only difference is that, recognising the different knowledge levels at entry, trainee BMS staff can complete the training in the shorter period of 18 months.

Individuals appointed to trainee BMS posts can come from a range of educational backgrounds:

- IBMS approved degrees for registration with the HPC
- Degrees which require to be “topped-up” before they can be approved by the IBMS for HPC registration
- Holders of co-terminus or integrated degrees
- IBMS approved Masters degrees

Candidates who apply for trainee biomedical scientist posts are encouraged to have their qualifications assessed by the IBMS.

Completion of the C&G Diploma should be a priority for trainee BMS staff in cytology although this will need to be balanced with completion of the portfolio that leads to HPC registration.

The IBMS Specialist Diploma Portfolio (Nov 2007) is designed to accommodate candidates who are studying towards the City & Guilds Diploma. Completion of this diploma is a mandatory component of the IBMS Specialist Diploma. Additional assignments to complete the Diploma are described within the portfolio.

Post registration training

After registration and completion of the City & Guilds Diploma and the Specialist Diploma, biomedical scientists can follow a career pathway of post-registration training and advanced qualifications. A framework of qualifications developed by the IBMS <http://www.ibms.org/go/education-development:professional-qualification> allows biomedical scientists to demonstrate their expertise and skills and aids career progression. Resources should be available to support staff to study towards qualifications within this framework and further education courses, for example, MSc in Biomedical Science.

2.3 Cytology Screeners (Agenda for Change Bands 4 -5)

Will hold the City & Guilds Diploma or its equivalent (IBMS / BSCC certificate of competence; NHSCSP Certificate in Cytology).

He can report samples screened or rescreened as negative or inadequate. All other cases MUST be passed on to a checker, consultant BMS or pathologist.

Cytology screeners may carry out any tasks suitable for MLAs, under supervision of a BMS. Such tasks may be used to break up the day and avoid exceeding the hours recommended for primary screening. However, these tasks should not prevent the cytology screener from being allowed sufficient time to carry out the cervical screening for which they are primarily trained.

A range of duties is listed on page 2 of NHSCSP document number 12.

<http://www.cancerscreening.nhs.uk/cervical/publications/nhscsp12.pdf>. The BSCC supports these recommendations and would emphasize the following.

They must:

- screen a minimum of 3000 cases per annum (see section 4.1)
- participate in the relevant regional EQA scheme
- undertake three days of update training every three years (see section 7.6)
- Participate in a properly documented Continuing Professional Development scheme such as that run by the NAC.
- Undertake four days of in-house training per annum
- Undertake the relevant formal documented in house training if returning to cervical cytology after a period of absence of more than three months. . If the absence exceeds six months then external training may be required.

2.3.1 Trainee Cytology Screeners (Agenda for Change Band 3)

A trainee cytology screener is an individual employed to be trained in the primary screening of cervical samples. They should not be employed on a less than 0.5 wte contract. Trainees MUST not report out any cervical screening reports or participate in routine rapid pre- or rescreening. They can be utilised to archive slides, support experienced staff in preparation duties and other tasks as deemed appropriate. Whatever extra duties a trainee may become involved in it is important that the employing laboratory allows trainees sufficient time to undertake both the practical and theoretical elements of the City & Guilds training programme, as indicated below.

Training and Education

In order to progress from the trainee to the cytology screener grade, staff need to complete the City & Guilds approved Diploma.

http://www.cityandguilds.com/44103.html?search_term=Cervical%20Cytology .

The minimum training period for the City & Guilds Diploma is two years irrespective of whether the individual is full or part-time.

Completion of the Diploma includes mandatory attendance at an approved introductory course and, approximately one year later, a follow up course.

In-service training should provide experience in appropriate procedures in order that trainees can become competent in all relevant aspects of cervical cytology. A departmental training officer should oversee the training of individual trainees and liaise with the appropriate training centre.

Supporting trainee staff through the Diploma should not be underestimated and training officers should be allocated sufficient resources and time to enable them to undertake this task. A minimum of four hours per week should be allocated to those undertaking this role. This would need to be increased where assessors have more than one trainee.

No trainee should be employed on less than a 0.5 WTE contract. For workload calculations trainees should be considered supernumerary.

2.4 Support Workers / Medical Laboratory Assistants (Agenda for Change bands 2 – 4)

MLAs perform a range of routine tasks in laboratories under the supervision of a BMS. Training is entirely in service and should have a formal framework. There are no minimum qualifications. An MLA training log must be kept and the MLA should be continually monitored. It is recommended that the MLA should be provided with an individual log book consisting of the appropriate extracts from the "Manual for Training and Competence Assessment of Medical Laboratory Assistants".

Further advice is available from the following link,

http://www.ibms.org/index.cfm?method=professional.about&subpage=mla_qualifications

This is under reconstruction at the current time. If there are any problems accessing the link please contact the IBMS via mail@ibms.org and they will be happy to send hard copies of the guidance.

The MLA job will consist of a number of tasks according to local requirements but the duties DO NOT include the screening of cervical samples.

2.5 Secretarial and Clerical Staff (Agenda for Change bands 2 – 4)

The large numbers of specimens received by cytopathology laboratories require the support of efficient clerical and secretarial staff. There are facets to clerical responsibility unique to cytopathology. Duties may include data entry, label printing, entering results, printing, collating and dispatch of results, archiving, telephone enquiries, and letters. All clerical support staff must be computer literate. An adequate number of clerical staff is important and needs to be properly calculated. This will depend on whether the cytology office is integrated with pathology and the opportunities for flexible working. A system using paper requests and reports may require 3-4 WTE for 50K samples per annum. A paperless

system with only occasional data entry, and queries and letters to be handled may need 0.75 WTE for the same workload. A pool of trained individuals to cover sickness/absence is essential. Screening time must not be compromised by the inappropriate use of skilled screening staff to perform clerical duties.

3. Management of Microscopy

3.1 Specimen receipt (see section 8 also)

A cervical cytology sample is viewed as a replaceable specimen. This means that if there is any concern about identity, the sample can be discarded. Errors of attribution of a sample and result to the wrong patient are very difficult to detect. Slides & vials must be labelled with appropriate identification. The minimum dataset is surname, forename or initial, date of birth and NHS number. (In Scotland CHI number). Request forms (paper or electronic) should be fully completed with the same minimum dataset as for the specimen. In the case of genitourinary medicine (GUM) the appropriate ID number should be in evidence.

If there is a minor discrepancy e.g. spelling error, transposition of a single digit, this sample may be accepted but the report must describe the issue and highlight the sender's responsibility to avoid in the future.

Absence of essential data or mismatch between the vial and the form constitutes a major discrepancy and represents a serious risk. Such samples should not be accepted. The vial should not be returned, rather a letter should be sent to the sample taker describing the problem and requesting a repeat. The vial should be destroyed. Multiple minor discrepancies constitute a major discrepancy. The laboratory quality management system must include a procedure for recording all cases where specimens are rejected and destroyed, and the reasons for rejection documented. Any cases where patient harm may have occurred must be reported through the organisation's incident reporting procedure. Regular audit of rejected specimens should take place.

If specimens arrive without a form or vice versa the samples taker should be contacted to see if there is a simple explanation. There must be a locally agreed protocol and SOP to deal with such cases.

Laboratories should keep a record of these samples, but this should not be on the laboratory computer system, as it is impossible to attribute these samples to an individual's records.

There must be a designated individual(s) who is/are responsible for those cases in which the minimum dataset is not met or if specimens / request forms do not match.

Further information in respect of specimen reception and minimum datasets is available in section 8.

3.2 Specimen requesting and clinical appropriateness

In England it is mandatory that box 20 on the request form (cervix fully visualised, 360 sweep) is ticked. If not the sample will be screened and reported if abnormal, but if no abnormal cells are seen it may be reported as inadequate (as recommended by the NHSCSP) or returned to the sample taker with a negative report indicating that if the cervix was not visualised and a full 360 degree sweep taken, then the sample should be repeated (as carried out by laboratories in the North East, Yorkshire & Humber SHAs). In Scotland it is mandatory to indicate in SCCRS that the cervix was seen but no requirement to record the 360 sweep. In Wales the request form states that "It is essential that the smear taker visualises

the cervix fully and samples it correctly with five 360 degree rotations of the sampler.... Submission of this sample with a signed request form is confirmation that this has been done.”

It is entirely acceptable, after adequate communication, for a laboratory to refuse to process samples taken outwith current NHSCSP screening intervals. However, this must be agreed with local commissioners and publicised to primary care and such samples should then be returned to the sample taker with the request form. A record should be kept of such samples which should be audited with all rejected specimens as outlined in section 3.1.

Where samples are taken from women attending genitourinary medicine (GUM) laboratories should encourage GUM clinics to inform any patients in whom a sample is indicated that if they do not waive their right to anonymity they may lose the benefits of appropriate follow up and failsafe procedures.

However, English laboratories should retain the ability to register a sample under a unique GUM number. In Scotland, samples cannot be entered on SCCRS unless full demographics are entered. In Wales it is strongly recommended that patient demographics are supplied but an anonymised sample will not be rejected.

3.3 Laboratory Preparation

NHS laboratories use one of two liquid based cytology (LBC) systems currently approved for use within the NHS. These are the ThinPrep® system marketed by Hologic www.hologic.com and SurePath™ <http://www.medical-solutions.co.uk/Cytology.aspx/> Both systems require a Cervex® brush to obtain a sample from the cervix, but the two systems differ in the method of preparation producing cell spots of different sizes and cell density. It is also vital to be aware that for the ThinPrep system the Cervex® brush is immersed and thoroughly rinsed into the PreservCyt™ sample vial. For SurePath™, the Cervex® head is detached and placed in the vial. With SurePath™ it is appropriate for primary care to place both the head of the Cervex® brush and any endocervical sampling device used into the same vial. Similarly the broom and endocervical sampling device can be rinsed into the same ThinPrep® vial.

3.3.1 SurePath specific preparation

The preparation of samples with the SurePath system is a semi automated process.

A certain amount of dexterity and attention to detail is required to ensure there is a robust chain of custody, and a high quality stained preparation to screen. All staff working in SurePath™ preparation must undergo the manufacturers training and be certified as competent before they can run the process. The process can be carried out by laboratory support workers with appropriate supervision by senior BMS staff who have also received appropriate company based training. Two WTE laboratory support workers are needed to process 35,000 samples per annum, but this requirement will rise if the staff concerned also work in other area e.g. specimen reception. It should also be noted that sufficient numbers of staff need to be trained to provide cover for annual leave and other absences from the department. Based on a 37.5 hour working week the system is capable of processing an annual workload

of approximately 50,000. A slightly longer working day (08.00 – 17.00) should permit this to rise to 60,000, which would require a minimum pool of four, trained individuals.

3.3.2 *ThinPrep Specific Preparation.*

Preparation of the sample can be by using the following instruments:

- TP-2000 is a bench top model which is loaded manually with individual pots and consumables. This processor is appropriate for workloads of up to 20,000 samples per annum
- TP-3000 is fully automated and allows for up to 80 samples per batch
- TP-5000 is a fully automated bench top instrument but is more flexible and can also process non-gynaecological samples and make multiple preparations from a single vial. It allows for processing in batches of 20, with an option to add extra pods which will enable up to 160 samples to be loaded

The machines require careful maintenance regimes. Slide preparation and machine maintenance should be performed only by laboratory staff, laboratory support workers or BMS, who have been trained by the manufacturers or individuals designated by the company. Based on a 37.5 hour working week the TP-3000 is capable of processing an annual workload of approximately 60,000 samples. The TP-3000 and TP-5000 requires only one or two staff to manage them on a day to day basis, but departments should have a minimum pool of four trained individuals to cover for absence, sick leave etc

3.4 Staining

All finished preparations should be stained by a Papanicolaou based method. All laboratories must participate in a relevant national technical EQA scheme. These are managed in England by the regional quality assurance teams and the protocols and operating procedures for this are included in NHSCSP document 15. <http://www.cancerscreening.nhs.uk/cervical/publications/nhscsp15.html>

Scottish laboratories and those in Northern Ireland must participate in the Scotland and Northern Ireland Cytology EQA scheme. In Wales the technical EQA scheme is run in keeping with protocols laid down in NHSCSP document 15, but administered by Cervical Screening Wales. Details of protocol and procedures can be found in the Quality Manual on the CSW website.

<http://www.screeningservices.org/csw/prof/quality/index.asp>

Currently, laboratories using the Hologic imager stain, should participate in the manufacturers own EQA scheme.

Each day staining quality should be checked and recorded.

3.5 Mounting / Coverslipping

Stained preparations should be carefully coverslipped to avoid air bubbles.

4. Primary Screening

Primary screening must be carried out by suitably qualified staff (as identified in section 2. Staffing). Irrespective of who is carrying out the screen ALL the material on the slide must be examined. There is little published evidence on the optimal method of screening, but whatever system or screening technique is used, individual screeners must overlap fields by at least 30%. It is safe to screen using a x10 objective, but in particularly crowded or difficult samples it may be safer to slow down considerably or screen using a x20 objective. The ideal overlap is unknown since it is a trade-off between screening speed and accuracy. There is no evidence base to support the practice of bi-directional or double screening of single samples and this practice should be discontinued.

NHSCSP publication No 14 <http://www.cancerscreening.nhs.uk/cervical/publications/nhscsp14.html> supports earlier BSCC guidance <http://www.clinicalcytology.co.uk/uploads/RCOP%201997.pdf> highlighting that one of the main problems in primary screening is maintenance of vigilance.

In order to create a safe working environment and optimise the performance of primary screening the BSCC makes the following recommendations:

- Screeners can safely undertake primary and rapid screening for up to five hours in any 24 hour period. No one should exceed this amount of time on primary or rapid screening.
- The working day should be organised so that there is at least one break from continuous screening of at least 20 minutes duration (a maxi break)
- This should be taken after no more than two hours at the microscope
- Regular mini breaks of several seconds should be taken every 10 – 15 minutes of microscopy
- A mini break of one or two minutes every 30 minutes is beneficial
- Other, non-microscopic duties, can act as breaks from microscopy
- Screening should only take place within the laboratory environment. Taking work home for screening is not permissible
- The BSCC recognises the fact that a number of screeners may work in more than one laboratory; however, the BSCC recommends that no screener works more than 6 days in any single week.

In order to prevent vigilance decrement and to facilitate the meaningful evaluation of screening statistics the BSCC recommend that laboratories try to ensure that samples from different sources (colposcopy v primary care) are shared equally between individual primary screeners.

4.1 Optimum Workload for Primary Screening

There is a poor evidence base regarding the optimum number of slides a primary screener should see in a year. It is intuitive that all staff whose primary duty is screening cervical samples should examine enough slides to maintain screening skills and to generate meaningful sensitivity calculations. With the advent of LBC traditional workload numbers could be re-evaluated, but the BSCC feel that that whilst numbers well in excess of 3,000 slides per annum are achievable, this figure still reflects a reasonable

minimum in terms of maintaining competence and allowing reasonable sensitivity calculations. This is irrespective of whether the individual is full or part time. Previous Codes of Practice from the BSCC indicated that those undertaking primary screening should NOT be employed on a less than half time basis (18.5 hours per week). Provided individual screeners reach the minimum of 3000 slides per annum the BSCC make no requirement on the minimum number of hours.

Productivity / screening rates are hard to evidence since staff perform many different duties and the amount of time available for primary screening varies between departments. After consultation with many laboratories the BSCC suggest that a suitable target would be 1000 slides per annum for each day worked, irrespective of whether full or part time. In other words, someone working three days should be able to achieve a minimum of 3000 per annum; those working four days 4000; and those working five days 5000. Clearly many staff will primary screen in excess of these figures and providing they are satisfying NHSCSP quality standards and are not undertaking primary and rapid screening for more than five hours per day and six days per week, the BSCC makes no recommendation about a maximum number.

It should be remembered that as more slides are screened, more rapid screening is generated, and managers should take this into account when assessing productivity rates for individuals or whole departments.

All individuals who undertake primary screening must participate in primary screening EQA.

4.2 Ergonomic standards for Primary Screening

Information on minimum ergonomic standards for laboratory, screening and clerical areas is well documented in NHSCSP document number 17

<http://www.cancerscreening.nhs.uk/cervical/publications/nhscsp17.html> The document includes ergonomic standards for chairs, benches, desks, PCs and a number of other areas. In addition there is information on posture and issues such as work breaks.

5. Checking

Checking is where cervical samples identified by primary screening as potentially abnormal are examined by more senior BMS staff. Checking varies by laboratory and may be of all abnormal slides submitted by the primary screener while others screen only the “difficult” slides passed to them by the screeners.

Checkers should be A4C band 7 or above, must have a minimum of five years experience in cervical screening, and hold the NHSCSP Certificate in Cytology or equivalent. Checking must not be carried out by cytology screeners.

The checker should examine the whole slide, paying particular but not exclusive attention to any marked areas on a slide. Ideally the checker should examine the slide before noting and addressing any concerns the primary screener may have regarding the case; this minimises interpretation bias. In cases where the primary screener has indicated that they suspect the sample is demonstrating high grade dyskaryosis and the checker considers the test to be negative or inadequate the slide should be passed to a second checker to spot review the slide before allowing it to be reported as such. If both of those checking the slide agree it is negative or inadequate, then the first checker should sign it out. Any case where the checker considers the slide to be abnormal should be passed to a consultant BMS or medical consultant for reporting.

The nature of the checking role will necessitate feed back to primary screeners on cases where there are differences of opinion. For this reason the checker should have access to a teaching microscope, preferably away from the screening room, where review of slides can take place.

Feedback from the consultant pathologist or consultant BMS on discrepant slides should be given to the checker on a regular basis.

In some laboratories checkers are not currently used. In these laboratories all samples identified as abnormal are passed directly to a medical consultant or consultant BMS. The BSCC recommends that all laboratories maintain the role of checking. It serves a valuable function in maintaining interpretive skills among more senior scientific staff and facilitates career development in relation to the Diploma in Advanced Practice.

Everyone who expresses an opinion on a slide must have their opinion recorded in a retrievable manner. The BSCC acknowledge that some consultant BMS staff will from time to time perform as a “checker”. Where this occurs it is logical that any cases deemed to be abnormal can be directly reported by the consultant BMS without the need for a third opinion. However, the BSCC recommend that in keeping with the suggested protocol for checkers (above) where the consultant BMS wishes to report cases as negative or inadequate that have been coded as high grade dyskaryosis by a primary screener these be shown to a second checker, consultant BMS or medical consultant for a third opinion.

The BSCC do not support the use of consultant BMS staff as checkers on a permanent basis. This is not an appropriate use of resources and will act as a barrier to the career progression of junior members of staff.

5.1 Optimum Workload for Checkers

Checking requires additional interpretive skills to routine primary screening. NHSCSP publication 12, <http://www.cancerscreening.nhs.uk/cervical/publications/nhscsp12.pdf> recommends checkers should see at least 750 cases per annum.

There is currently no guidance on the amount of time that checkers can safely undertake microscopy per working day. Because the nature of checking is very different to that of primary screening the BSCC acknowledge that checkers may exceed 4/5 hours of microscopy and provided that regular breaks are taken it is acceptable for checkers to undertake microscopy beyond this time. There is no literature

covering this area, but the BSCC would accept that, provided it is not occurring on a daily basis, this period could extend to a normal seven and a half hour working day. The BSCC do not recommend that microscopy duties extend beyond this period of time in each 24 hour period.

Where the checker has already undertaken primary or rapid screening in that working day a suitable break MUST be taken before proceeding to checking of slides.

5.2 Training and Education

At present there is no recognised qualification to enable checkers to demonstrate competence in this role. Before a BMS takes on the full reporting role of a checker there should be a period of documented in-house training or shadow reporting, audit and review. The lead medical consultant takes responsibility for the cases signed out by the checker as negative, and as such he should be satisfied that the checker has sufficient experience and training at this level.

6. Reporting by Consultant BMS and Medical Consultants

All slides passed to a consultant BMS or a medical consultant must be carefully examined, paying particular but not exclusive attention to any marked areas on a slide. Ideally this should be done before viewing what concerns the primary screener and checker may have regarding the case to minimise interpretation bias. To enable meaningful comparison of consultant BMS / medical consultant performance statistics laboratories should try and ensure that individuals receive a balance of routine versus colposcopy work

Where the consultant BMS or medical consultant wishes to report a sample coded as high grade dyskaryosis or glandular neoplasia by a primary screener or checker as negative or inadequate then the BSCC recommend that the slide be shown to a second medical consultant or consultant BMS before reporting.

6.1 Optimum Workload for Consultant BMS and Medical Consultants

Interpretive skills are of paramount importance to staff reporting abnormal cervical samples. In laboratories where there are several staff who want to continue reporting abnormal cervical samples it is recognised there may be an element of competition to maintain reporting numbers. However the BSCC recommends such staff see a minimum of 750 referred cervical samples per annum. This can be achieved by ensuring that the minimum yearly workload is not be less than one programmed activity in cervical cytology <http://www.rcpath.org/resources/pdf/GuideHistoCytoWorkload0605.pdf> which equates to 500 screening cases. Further samples will be reviewed for example for audit and correlation purposes. These are in addition to the requirement for screening cases, and will in most cases result in the individual's workload exceeding 750 cases/year. (see 7.5.2)

7. Quality Assurance

7.1 Rapid Screening

The BSCC recommend that rapid screening is the method of choice for routine quality control of primary screening. As well as being the most cost effective way of preventing false negative reports leaving the laboratory, rapid screening also allows monitoring of the accuracy of screening within the laboratory and reliable comparisons between individual staff members. Because rapid screening involves looking at all negative and inadequate samples it is also capable of identifying patterns of poor performance very quickly and this is the big advantage over other forms of quality control such as rescreening 1:10 slides.

It must be remembered that such monitoring is dependent on the accuracy of reporting by all staff members at all levels, i.e. poor rapid screening can give false re-assurance whilst over zealous reporting by checkers and pathologists can lead to apparent poor performance.

Since the publication of NHSCSP document number 1 in 1995

(<http://www.cancerscreening.nhs.uk/cervical/csp01.pdf>) rapid screening has been compulsory for all NHSCSP laboratories.

The BSCC makes the following recommendations:

- Rapid screening must only be carried out by qualified members of staff
- There is no evidence as to the ideal technique for rescreening and no single technique is recommended. However the rescreen should take approximately one minute to 90 seconds and aim to cover a representative area of the cellular material. No individual should rapid screen more than 50 tests in a 24 hour period
- Individuals should undergo basic training in the different skills and techniques involved in rapid screening before they are permitted to carry it out
- Some form of in house assessment or evaluation should be undertaken after the first month
- Rapid screening itself should be subject to quality management* (see below)

7.2 Rapid rescreening versus rapid pre-screening

Rapid pre-screening was used extensively in early papers describing the utility of rapid screening since one of the original aims was to identify abnormal tests within laboratory backlogs. It has subsequently been suggested that rapid pre-screening may be more effective than rapid re-screening in that it addresses the problem of expectation of normality inherent in rapid screening carried out after the primary screen, where most of the abnormal tests have already been identified and removed. If rapid pre-screening is used then the laboratory must ensure that any abnormal samples identified on rapid pre-screening are not removed or marked in any way and that all the original slides (normal & abnormal) are included in the primary screening workload.

The results of both arms must be completely blinded to each other and carried out by different individuals.

Rapid pre-screening has the added advantage of allowing for continual assessment of an individual's rapid screening performance. Pre-screening data should be kept for each screener with rapid screening results compared with the final outcome following primary screening. Whilst there is little data regarding acceptable performance at rapid screening there is literature suggesting that a sensitivity of around 70% is achievable ^(1,2).

Where rapid rescreening is used then data relating to the number of samples identified as abnormal or in need of further review versus number of cases rescreened should be kept for each individual.

Comparison of rates within the department over a rolling year should indicate where performance might be below average.

7.3 Assessing the Performance of Individual Screeners

The assessment of individuals carrying out primary screening is well described in NHSCSP publication number 1 <http://www.cancerscreening.nhs.uk/cervical/publications/cc-02.html> The BSCC support the evaluation of individual primary screeners via rapid screening and the original sensitivity criteria of 90% for all abnormalities and 95% for high grade abnormalities. However the BSCC also acknowledge the limitations identified by the NHSCSP working group and reiterate that all sensitivity data must be considered alongside other indicators of performance such as pick up rates, workload numbers and type and any other information relevant to individual performance. In particular, sensitivity calculations must be based on data collected over a sufficient period of time. The BSCC suggest that data be evaluated every three months, but over a full rolling year. Because of small numbers it is unlikely that meaningful figures can be extracted from data collected over a shorter period. It is also important to look at when any false negative samples were reported in order to ascertain whether there is a pattern. It is not unusual for performance to dip from time to time and prolonged poor performance would be of greater concern than temporary. Prior to any formal discussion it is also prudent to look at the samples in question and any histological outcome. It is well recognised that high grade abnormality may be overlooked if there are only a few abnormal cells present ⁽³⁾ and this must be taken into account.

7.4 Management of poor performance

It is recommended that all cytology units have a designated individual who is responsible for collecting and monitoring sensitivity data. This might be a designated quality manager, but could be the lead BMS or raining officer. When identifying individual poor performance it must be remembered that single errors or a small number of errors are inevitable in screening as is some statistical variation in the pick up rates of individuals. Such errors and variations should not result in inappropriate over-reaction. Nevertheless, if such errors form part of a pattern then they should be investigated. Whilst the BSCC accept that there is no one course of action that will apply in all cases, this and any likely actions in cases of poor performance must be clearly documented in departmental Standard Operating Procedures (SOPs). Any SOP should also outline clear lines of responsibility and the importance of clear

communication between everyone concerned, but in particular those managing the poor performance and the lead BMS and lead medical consultant.

It is also vital that any actions or investigations are carried out in the appropriate manner. Any discussions must remain confidential and care must be taken to limit the stress on individual staff concerned. All investigations, actions etc must be clearly logged and minutes taken of any formal discussions.

It is also very important that there are adequate resources for support and retraining where necessary.

Options to be considered in the case of 'poor performance' include: -

- In house training
- External training (refresher course)
- Directed learning (where a particular problem area is identified)
- Temporary suspension from cervical screening (in the cases of problems with concentration due to personal problems/illness etc with an opportunity for educational updates on return to screening/checking/reporting)
- Increased time/case load/opportunity for cervical cytology (in a case where experience decreasing due to other work pressures)

The BSCC recommend that following any suspension from screening any return to normal, unsupervised screening should be after an agreed period of double screening and careful monitoring. If any high grade cases are "missed" during this period then a period of further monitoring should be instigated.

7.5.1 Assessing the Performance of Individual Checkers

The role of the checker is poorly monitored and there is currently no guidance on what proportion of referred slides the checker should be referring to consultant staff.

Also, there is currently no guidance on quality control, assessing competence or performance monitoring of this role. Checkers frequently report referred abnormal slides as negative without another opinion being sought.

Systems to record data to permit performance monitoring of checkers should be implemented. The facility to compare the opinions of primary screeners with the checkers opinion should be part of the system specification for LIMs. Whilst there is no agreed ideal figure for referral rates by checkers this will permit overall and individual checker referral rates to be calculated and compared. In addition the percentage of slides referred as abnormal but changed to negative by a consultant BMS or medical consultant should be monitored and compared across individual checkers to identify outliers.

7.5.2 Assessing the Performance of Individual Consultant BMS and Medical Consultants

Whilst recognising that positive predictive values are subject to other variables such as type and reporting of any biopsies, regression of lesions, accurate follow up etc they should be calculated for all

staff reporting abnormal samples. Care should be taken to ensure that those reporting such cases receive a randomised workload.

Calculation of positive predictive value (PPV) is outlined in NHSCSP document Number 1

<http://www.cancerscreening.nhs.uk/cervical/publications/cc-02.html> and should be calculated for all samples reported as showing moderate dyskaryosis or worse. This should be done on a rolling 12 monthly basis every three months. It must be noted that for PPV to be truly representative it must be calculated on a minimum number of 200 cases. Many individuals will not reach this figure in a given 12 month period. Where 12 monthly PPVs are too low or high it might be prudent to recalculate these over a longer rolling period.

PPVs should be calculated on an individual basis and reporting consultant BMS and medical staff should be compared both within individual units and with national standard ranges as outlined in the annual statistical bulletin. Performance outside the norm may not necessarily indicate poor performance and care should be exercised when investigating such results. Where there are concerns over individual performance it might be useful to look at total predictive or abnormal predictive values (TPV & APV) as indicated below. Remedial action should only be taken where appropriate and should be recorded. The lead consultant is responsible for this. Where poor performance involves the lead consultant then that individual's line manager should be informed.

7.5.2.1 Total Predictive Value / Abnormal Predictive Value

As indicated above, where PPV calculations are based on small numbers of high grade abnormalities (less than 200 per annum) those interpreting the results must be aware of the large confidence limits. In these cases, or where there is concern over an individual's performance it may be of value to calculate total predictive or abnormal predictive values. APV is the proportion of low grade abnormalities that turn out have high grade CIN and can be calculated from KC61 data. This can be added to PPV data to give a total predictive value. The advantage of TPV is much greater statistical stability than PPV because it incorporates more data from the KC61 part C2. In Scotland SCCRS will generate PPV reports for individuals and laboratories. APV and TPV can be calculated using Business Objects queries. In Wales, Cervical Screening Wales (CSW) produces statistical data 6 monthly and both laboratory and individual consultant PPV is calculated.

Since they are not published nationally it is impossible to compare TPV across different laboratories, but as the percentage of referrals from borderline + cytology with a final diagnosis of CIN 2 or worse, it can give extra information on individual reporting rates within a unit. Importantly this would allow useful comparisons between individuals reporting in the same unit should PPV data highlight potential differences.

Although there has been much less investigation of suitable values for APV or TPV observed data for 2004/5 suggests that to ensure a 'reasonable' specificity at least one in three referrals from borderline or worse should have histology of CIN 2+, i.e. treatable disease and therefore a TPV below 33% could be viewed as an indicator of less than satisfactory performance.

An audit of the laboratories in the North West for 2006-7 demonstrated a range between 32.8% and 52.7%, with only one lab below 33%.

APV is a much less robust figure and although useful when added to PPV to give a TPV, care must be exercised in evaluation of APV in isolation. Because it measures the proportion of low grade samples with a high grade outcome it is invariably related to reporting ethos. In other words laboratories aiming for high specificity will have a high APV, whilst those aiming for maximum sensitivity will have a low figure.

7.6 Continuing Education

Quality assurance is more than assessment of performance and in addition to assessment of performance the BSCC recommends that all individuals practising in the NHSCSP participate in relevant continuing education schemes and activities. All medical consultants, including those employed on a part time or locum basis or in private practice, must maintain their licence to practice with the General Medical Council (GMC). To do this, evidence of successful participation in CPD will be required. More information on this is available from <http://www.rcpath.org/index.asp?PageID=622>

With regard to non medical staff all BMSs have to undertake CPD in line with HPC regulations http://www.hpc-uk.org/assets/documents/10001314CPD_and_your_registration.pdf For cytology screeners the BSCC support NHSCSP guidance

<http://www.cancerscreening.nhs.uk/cervical/publications/nhscsp12.pdf> as outlined in section 2 of this document, which states that individuals should undertake four days of in house training per annum. The BSCC is not prescriptive about how these days are provided: training may comprise CPD type lectures, grand round talks, slide review meetings and other activities such as journal based learning. The laboratory training officer should ensure that all staff record these activities in individual portfolios. Where possible slide review meetings must take place at least once per month and all staff should be encouraged to attend. Where this is not possible because the department does not have access to a multiheaded microscope or TV system, laboratory training officers must make sure that interesting cases are circulated around all staff, including medical consultant and consultant BMSs.

7.7 External Quality Assurance (EQA)

Any individual reporting cervical cytology samples in the UK cervical screening programmes must participate in a recognised EQA scheme. These are managed and run by the regional quality assurance reference centres or equivalent in Scotland, Wales and Northern Ireland). Details of the scheme are available from QA centres or via the NHSCSP website:

<http://www.cancerscreening.nhs.uk/cervical/publications/nhscsp15.html>

8.0 Requirements of a cervical cytology laboratory information technology (IT) system

8.1. General aspects

8.1.1 Providers

IT systems should be provided by organisations which are able to give ongoing support. Support should not be dependent on an individual or small group of individuals.

The system should run on an organisational network and should be subject to all the regulatory structures of the organisation.

The laboratory should have a named individual, usually a BMS, with lead responsibility for IT.

8.1.2 Functions.

All functions should be as intuitive as possible. Menu choices should include text rather than code only. The entry of important decisions, such as final result and recommendation should be a two stage process in that a selection from a set of alternatives is made then the selection made is displayed and the user asked to confirm. Wherever possible rule based systems should be used to prevent the user making an illogical or forbidden decisions.

8.2. Storage of patient data and results

Patient data and results should be electronically stored indefinitely. Duplicate patient entries should be avoided and the system should conform to wider organisational policies on merging duplicate records.

8.3. To allow controlled electronic access

Staff should have access rights dependent on their role. It will be appropriate for staff in cytology to have access to all current and previous histology and cytology results for all patients, including laboratory comments which are not included on the final report

Clinical staff in a hospital or general practice setting may have electronic access if they require it for patient management and subject to all organisational security protocols, but only to completed authorised reports, (in SCCRS sample takers can track samples before they are reported) and only to the data items included on the final report. General practices have access only to their own patient records. Regular audit of data access should be carried out

8.4. To administer the receipt, processing and reporting of cervical cytology samples

The following are mandatory functions of any IT system;

8.4.1 Recording and presenting on demand the demographic and clinical details supplied with a specimen

Sample requesting may be either electronic or by a paper request form. Paper data requests must be transcribed onto the system. Adequate training must be given and accuracy of data entry must be kept under review.

The demographic details recorded for each woman should include name, forename, date of birth, NHS number (or CHI number in Scotland), current address, correspondence address (if different), and general medical practitioner. At least three patient identifiers must be present to allocate a sample to a certain patient. If two identifiers are present, remaining data can be sourced from other systems e.g. hospital PAS data base.

If samples are not adequately identified they should not be accepted (see section 3.1)

The sample specific data held against each sample request must include all the data submitted on the request form, including free text clinical details.

When the sample request data is submitted on a paper request form a copy of the request form (either on paper or in electronic form as a digital image) should be retained for 3 months.

The minimum data set is discussed in section 3.1, but in terms of patient registration required data items are;

- Surname
- Forename
- Surname at birth and any previous surnames
- Address + Postcode
- Correspondence Address i.e. address to which the woman's copy of the result is to be returned (if different from registered address)
- Date of Birth
- CHI number (Scotland)
- NHS Number
- GP name and address
- Sender's Details -There should be facility to record the sample taker identification. Sample taker registers are acknowledged to be good practice and may be administered by laboratories, PCTs or national computer systems. Whichever system is in place locally the laboratory system needs to be able to record in a searchable field the sample taker identity.
- Date cytology sample taken
- Previous cytology result
 - Previous cytology results should be available either manually, added by requestor, via SCCRS in Scotland or as an Exeter system download. As a fall back laboratories can use their own data base or look up on Open Exeter so previous results though helpful are not mandatory.
- Clinical details
- Specimen status *NHS/Private*

- Last menstrual period
- Type of cytology sample: *cervical or vaginal vault*
- Appearance of cervix: *normal, suspicious, or not seen*
- Confirmation that the cervix was fully visualised and a 360° sample was taken
- Clinical Comments: *Free Text*

8.4.2 Recording allocated accession numbers

This may be a function of the IT system. Alternatively, numbers may be allocated manually and then entered into the system (see below).

8.4.3 Printing slide labels

It is possible to run a small laboratory without electronically generated slide labels, but this requires manual labelling of slides which is not practical in busy settings and increases the risk of error. Slide labels must be compatible with other technology used e.g. automated LBC or imaging.

8.4.4 Recording and displaying current clinical details and previous history of histology and cytology performed at that laboratory

Systems should be able to provide both current clinical information and previous cytology and histology histories, preferably by LIMs or if not via a paper record. The woman's entire cytology history should be accessible via Open Exeter access in the laboratory.

8.4.5 Recording opinions on a specimen and compiling the final result on that specimen,

All individuals who have an opinion (trainee cytology screener, cytology screener, checker, rapid screener, trainee pathologist, medical consultant, consultant BMS) must be recorded on the system. Ideally all individual results must be in searchable fields but it is mandatory that the results of the primary screener, rapid reviewer, checker and consultant are in searchable fields.

- The system must record diagnostic codes in accordance with the national cervical screening programme system in use. Systems should include provision to alter this feature should terminology change. This may include a requirement to record HPV test result and possibly HPV vaccine status.
- Recommended management should be recorded in line with national cervical screening programme requirements

8.4.6 Entering the result

The date of each opinion, the author of each opinion and the person inputting each opinion must be recorded. It is completely acceptable and in many ways preferable for all individuals to enter their own results.

8.4.7 Authorising the final result,

- All reports must have a primary screener opinion and at least one other opinion.

- Negative and inadequate results may be finally authorised by any qualified member of screening, BMS or medical staff.
- No report may be issued with a result of borderline changes or worse without the opinion of a consultant BMS or a medical consultant.
- Any report with an consultant BMS or medical opinion can only be authorised by an consultant BMS or a medical consultant.

8.4.8 Issuing results to call/recall data bases in England or other central data base

- In England and Wales the computer system must allow mapping of laboratory codes to standard national result codes for the NHSCSP (R, A, S, H). This should ideally be an automatic function.
- In England, results should ideally be transmitted to the data base electronically. Paper data transfer is slow and prone to errors of transcription and is strongly discouraged.

8.4.9 All laboratories should produce a computer generated report.

Card/carbon paper systems are no longer appropriate.

8.4.10 Issuing of amended results and maintaining an audit trail including the original result and any amendments,

It must be possible to record the reason for significant changes in data items (in particular changes in result and management) in an accessible form on the laboratory system. It must also be possible through an audit trail to ascertain who changed any item, when it was changed and the nature of the change. Results should only be changed when an error has been discovered, e.g. wrong management. Change of diagnosis code, for example following an MDT, should not generate an amended result code, rather a supplementary text report should be produced. This should include the fact, the date and the reason for the change and the name of the person authorising the change.

8.5 To generate data to monitor the laboratory and the programme

- Workload
 - Data for individual members of staff and the laboratory overall is required
- Production of nationally specified statistics
 - KC 61 or equivalent
 - Sample taker result profiles and activity.
- Production of internal quality assurance data.
 - Current mandatory items are sensitivity for all grades and high grade dyskaryosis for all primary screening staff, and PPV for consultant medical and consultant BMS staff, as well as overall laboratory sensitivity and PPV
 - Calculation of additional monitoring information such as APV, TPV is desirable together with the flexibility to produce ad hoc queries to cover the needs of the service.

- Searching by diagnostic code for internal audits, identifying training material etc.

8.6 To administer laboratory failsafe

- The system must have a function to identify women who are the subject of laboratory failsafe i.e. women with a result of moderate dyskaryosis or worse, and women referred to colposcopy with low grade changes.
- Determining which of these women have not had a subsequent histology result will require manual intervention in most settings, but if the system is able to automate any part of the process this is advantageous
- The system may be used to produce standard result letters

8.7 To be compliant with security requirements

The security of the data is paramount. This means both controlling access to the data and ensuring that it is not corrupted or lost once entered.

Access to computer systems should be by individual login and passwords. National guidance on password selection and privacy should be followed.

Individual user profiles must be set up to allow appropriate access for that user.

It must be possible to audit any individual's activity on the system and to identify the individual responsible for entering or subsequently changing any data item. Users should be made aware that such an audit system exists.

The access rights of former users who no longer require it must be terminated without delay.

The system and the data must be adequately backed up, at least daily.

Patient identifiable data must only be stored on suitably protected systems such as Trust IT systems. All data protection policies of the host organisation must be adhered to. In addition, departments in England and Wales must meet the requirements of section 251 of the NHS act 2006 (Previously section 60 of the Health and Social Care Act (PIAG)) for data security for screening cases.

<http://www.dh.gov.uk/ab/PIAG/index.htm> or <http://www.cancerscreening.nhs.uk/section-60.html>

No patient identifiable data may be transmitted by email other than between two secure NHS addresses (currently those ending .nhs.net)

9.0 Terminology

The proposed revised BSCC terminology published in 2008⁽⁴⁾ has not yet been adopted by the NHSCSP. Departments are advised to use and record subcategories of borderline changes or glandular abnormalities as suggested by the revised terminology document to enable future audits and aid discussions on the potential value of such sub divisions.

10. Unreported cases and turn-around times

All departments must ensure that they keep records of samples reported in order that any unreported cases can be identified. Whilst the lead cytopathologists is responsible for ensuring that unreported cases are identified and turnaround times are monitored, there should be a nominated BMS responsible for monitoring this on a day to day basis. With regards to turn-around times by the end of 2010 all samples must be reported within 14 days. This 14 day period is from the sample being taken to the woman receiving the result.

Turnaround times should be monitored on a regular basis and communicated to those commissioning the service.

It must be remembered however that strict application of this standard may compromise other quality standards and care should always be taken to ensure that the quality of reporting is never compromised by the need to get results out within a designated timescale.

11. Laboratory Failsafe.

The aim of failsafe guidance is that should a planned action within the complex organisation of cervical screening fail there is a mechanism in place that enables the process to revert to a safe state, ensuring that the appropriate outcome is attained for each woman.

Guidance on failsafe systems and actions for the cervical screening programme is comprehensively detailed in the NHSCSP Publication No. 21 – Guidelines on Failsafe Actions for the Follow up of Cervical Cytology Reports <http://www.cancerscreening.nhs.uk/cervical/publications/nhscsp21.html>.

The responsibilities of the various organisations involved in the programme, including the laboratory, are clearly set out. The fulfilment of the responsibilities is assured and monitored by the regional QA Directors and their teams. NHSCSP document No.20

<http://www.cancerscreening.nhs.uk/cervical/publications/nhscsp20.html> clearly states that laboratories must operate and record failsafe procedures for women who require referral to colposcopy.

Many laboratories now directly refer women to colposcopy to ensure the waiting time standards for women with suspected cancer are met. The direct referral system is efficient and effective, but requires close cooperative working between the laboratory, colposcopy and general practice. The NHSCSP guidance for laboratories with respect to direct referral is expanded in this BSCC code of practice.

11.1 Responsibility for direct referral

The Hospital Based Programme Coordinator (HSBPC) is responsible for ensuring that:

- procedures are in place in both colposcopy and the laboratory and to support the direct referral process
- a mechanism is in place to facilitate the referral of urgent cases under the two week rule and that there is a formal written trail (i.e. fax / letter) confirming any verbal report.

Colposcopy (the colposcopist or nurse colposcopist) is responsible for:

- contacting and informing the woman
- inviting the woman to attend for a colposcopic examination
- informing the GP of the result of the invitation/treatment

The GP is responsible for further action should the woman fail to attend colposcopy.

11.2 Failsafe for Direct Referral

The laboratory should:

- follow the initial referral to colposcopy with a letter or email confirming that referral has been made
- initiate a failsafe enquiry six weeks after the date of the test result to confirm with the colposcopy unit that the woman has been seen
- contact the GP or responsible clinician if the woman has not attended (this failsafe action may be undertaken by the colposcopy unit if defined within the local standard operating procedure)

Please note that women who are urgently referred are on failsafe default of four weeks. Further guidance may be found at page 10 of NHSCSP publication 21.

<http://www.cancerscreening.nhs.uk/cervical/publications/nhscsp21.html>

In Wales, responsibility for direct referral and follow up of abnormal cytology is primarily the responsibility of the Regional Programme Coordinator. Details of the protocols and procedures can be found in the CSW Quality Manuals: <http://www.screeningservices.org/csw/prof/quality/index.asp>

12. Laboratory Audits

12.1 Invasive Cancer Audits

The audit of invasive cancers of the cervix is an integral component of the understanding of cervical cancer development. All laboratories must participate in the audit of invasive cancers audits as described in NHSCSP publication 28 <http://www.cancerscreening.nhs.uk/cervical/publications/nhscsp28.html>

The HBPC (or equivalent in Scotland, Wales & Northern Ireland) should be responsible for the audits and liaise with their regional QA centre with regard to collation and statistical support.

Where cervical cytology and subsequent histology from the same patient are reported in different laboratories there should be a robust system to ensure transfer of information and that slide review can be accomplished according to the guidance in a timely manner.

Wales has developed the Cervical Screening Wales Audit of Cervical Cancer (CSWACC). All cervical cancers diagnosed in Wales will be audited using the CSWACC protocol. The Regional Programme Coordinators have responsibility for the audit. Any cross border requests for audit of slides or biopsies in Wales should be made directly to the Programmes Coordinator concerned or through the CSWACC website.

12.2 Other Laboratory Audits

Routine audit of all sample reporting is integral to maintaining high standards of reporting. Information on overall performance is available via calculation of APVs, PPVs, and TPVs in accordance with section 7.5.2. However, laboratories should also consider auditing various sub categories. In particular borderline changes (especially where different sub types are used e.g. BNC HG), mild dyskaryosis and glandular abnormalities should be routinely audited to ensure reporting practices are sufficiently robust. Audit should include overall calculation of outcomes, but in addition some component of slide reviews. This could include cases of mild dyskaryosis or borderline change found to have CIN III. All cases of severe dyskaryosis or glandular neoplasia that have a subsequent negative outcome should be reviewed at CPC / MDT (see section 13) and records kept.

In addition to the mandated audit of invasive cancers laboratories should routinely audit the slide histories of all cases found to have high grade CIN at colposcopy and review any cases reported as negative or inadequate in the previous screening round. Such cases may have been erroneously reported and as such slide review may offer significant educational value.

13. Multidisciplinary Working

Cytopathologists are key members of gynaecological cancer multidisciplinary teams (MDTs) at cancer units and centres. The role of the unit team is to provide care for patients within their local catchment area whilst centre teams provide specialist care for their referring catchment area including their local catchment area. There is observational evidence that this framework of a group of professionals from different health care disciplines each able to contribute to diagnostic and treatment decisions at MDTs using agreed clinical guidelines improves outcomes and is valuable for postgraduate education. The MDT meeting is now well established as good standard practice essential to making timely, corporate and accurate decisions about patients.

MDT working was established as one of the essential standards for cancer care following the Calman-Hine report – ‘A Policy Framework for Commissioning Cancer services (1995)

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4071083

Guidance involving advice and recommendations on how teams should be set up with responsibilities and job descriptions for key team members is set out in the NICE IOG (Improving Outcomes Guidance for Gynaecological Cancers 1999, updated 2004). The technical measures for assessing a service against standards, particularly useful for self assessment and team development, are set out in the NHS Manual of Cancer Services 2004 with additional information published in New Gynaecological Measures in Relation to Diagnostic Services 2007.

All cases of cervical cancer must be reviewed at the gynaecological cancer centre MDT.

13.1 Clinicopathological conferences (CPCs)

The BSCC recommend that individual departments set up regular CPCs to review both mismatched cases and enable discussion of management in individual cases. As a minimum all cases of severe dyskaryosis or worse that do not have histological confirmation of high grade CIN should be reviewed. Notes and review opinions from these meetings should be kept both in the patient records and in a separate CPC file or database.

The frequency of such meetings should be in response to clinical need, ideally every month, but as a minimum six per annum.

Members of the MDT should include representation from the cytology laboratory, histopathology laboratory and colposcopy clinic. The chair of the meeting should be a member with a management role in delivering the local screening programme e.g. hospital based coordinator, lead colposcopist, lead for cytology, lead for histopathology.

14. The retention and storage of pathological records and archives

Detailed information on this produced by a joint working party of the RCPATH and IBMS was published August 2009. It is available from the respective websites

<http://www.rcpath.org/resources/pdf/g031retentionstorageaugust09.pdf> or

<http://www.ibms.org/go/media-centre:publications:professional-guidance>

14.1 Request forms

Should be kept until the authorised report has been received by the requester. As this period of time may vary with local circumstances, a minimum retention time is not stated, but ordinarily request forms need

not be kept for longer than one month after the final checked report has been dispatched. For many uncomplicated requests, retention for one week should suffice.

14.2 SOPs

Both current and outdated protocols should be dated and kept at least 30 years on file

14.3 Laboratory file cards or other working record of test results for named patients

These should be kept for two calendar years.

14.4 Records of telephoned reports

A log should be kept on the laboratory record of the relevant report or a hard copy should be kept for two calendar years.

14.5 Reports

Reports and copies (physical or electronic)

Hard copies should be kept for six months or as needed for operational purposes. This would be an indefinite period if there is no laboratory electronic record. Where copies represent a means of communication or *aide memoire*, for example at a multidisciplinary team meeting or case conference, they may be disposed of when that function is complete. Copies of reports sent by fax, with accompanying details of the date and time of transmission, and the intended recipient, should be retained in conjunction with the matching specimen reports stored long-term by the laboratory. Any such copies generated to substitute for an original report (e.g. if an original is misplaced) should be retained as for the original.

Electronic copies should be kept indefinitely.

14.6 Internal quality control records

Records of current and past quality control procedures should be kept for at least ten years.

14.7 Slides

Must be kept for a minimum of ten years.

14.8 Retention of samples

The retention of slides for teaching appears to be covered by the following statement in the document: “There are reasons why individual pathologists or heads of departments may wish to retain documents or materials for periods that are longer than the minimum times recommended here. The following reasons are legally permissible without patient consent, largely because they are regarded as a necessary part of the process of providing healthcare;

- Further diagnoses or ongoing clinical management.
- Clinical audit and quality control.

- ***Teaching and training healthcare staff.***
- Epidemiology.
- Analysis of data (such as case mix) for administrative or other purposes.
- Direct evidence in litigation.
- Individual, active research studies

It is nevertheless appropriate, when practical, to check that the patient has not lodged a specific objection to such use during the normal consent processes for the procedure(s) they have undergone.”

15. Transport of slides

15.1 Confidentiality of Slides during Transport

The use and security of personal information is subject to the provisions of the Data Protection Act 1998 and unauthorised disclosure of personal information is a criminal offence under the Act. All staff who handle patient identifiable data for the cancer screening programme must be familiar with the current guidance. Information is available on; <http://www.cancerscreening.nhs.uk/section-60.html>
In order to comply with the Data Protection Act 1998, under no circumstances must patient identifiable data be written on the outside of the slide transport packaging.

15.2 Labelling of Slides for Transport

All slides must be suitably labelled to ensure that the receiving laboratory is able to identify the slides. Labels must be securely attached to the individual slides.

15.3 Packaging Slides for Transport

All slides for transportation must be packaged in a way which prevents damage of the slides and which preserves patient confidentiality. Slides should be placed in a sturdy container, specifically designed for slide transportation. Any patient identifiable data which is being transported with the slides should be placed in a sealed envelope, marked 'Private and Confidential' and addressed to the person to whom the slides are being sent.

Both the slide container and the envelope containing patient data should be placed in a suitably sized 'Jiffy Bag'-type envelope.

The envelope must be clearly marked with the name and address of the recipient on the front. A return address must be clearly visible on the reverse of the envelope. The package must be clearly marked 'FRAGILE'.

15.4 Method of Slide Transport

Slides should be transported by a reputable courier firm or sent by secure mail delivery. Ideally contact must be made with the receiving laboratory in advance, to agree a date on which they will be sent and delivered. Where possible a named contact person should be nominated who will be available to accept and sign for the slides on the stipulated arrival date.

16. Quality Assurance Reference Centres

Quality assurance reference centres in England are tasked with monitoring the quality of all aspects of the cervical screening programme against standards published in NHSCSP guidance documents. They identify practice which is outside the norm and coordinate investigation to assess if this represents a real problem. Information is gathered through a process of questionnaires, multidisciplinary visits and a variety of other means. Quality assurance teams (QATs) also seek to identify and disseminate good practice. Similar structures are in place in Scotland, Wales and Northern Ireland

The essential components of regional quality assurance are:

- The QA director should report to and be accountable to the Regional Director of Public Health (RDPH)
- Operate a regional QA reference centre
- Establish a multidisciplinary QAT which must undertake QA visits at least once every four years
- Coordinate professional activity within the QATs
- Oversee and validate Department of Health returns
- Act as a key part of the team for handling screening incidents
- Work in close partnership and collaboration with the national office of the NHS Cancer Screening Programmes
- Facilitate EQA for cytopathology (including technical EQA)
- Monitor participation by all relevant professionals in national audit and EQA activities
- Monitor invasive cancers
- With commissioners of services, contribute to the development of health improvement programmes (HImp). Seek to establish that screening services are properly reflected within service level agreements and financial distribution arrangements
- Oversee integration of new technologies into the screening programme
- Liaise with CPA (UK) Ltd

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Glossary of Terms

| | |
|----------------------------|---|
| Primary Screen | In initial full screen of a cervical sample taking between 3 – 8 minutes. All the cells must be viewed by careful use of overlapping fields. |
| Rapid re-screen | A re-examination of a cervical sample reported as negative or inadequate as part of routine quality control. The whole of the sample is covered, but in large field jumps. Should take between one minute and 90 seconds |
| Rapid Screen | A rapid examination of all samples prior to a full primary screen. Should take between one minute and 90 seconds |
| Examine | Slide examination can be a full screen of the sample, but is taken to refer to a second view of the slide that may involve review of specific marked areas and / or full review |
| Checking | Is a second examination by a more senior member of staff of a sample reported by a primary screener as abnormal or indeterminate. |
| Programmed Activity | Full time medical consultants work a 40 hour week divided into 10 Programmed Activities (PAs), each of 4 hours duration. Typically these are divided into 7.5 PAs direct clinical care (specimen reporting, MDTs, one stop cytology clinics etc) and 2.5 supporting professional activities (CPD, audit, teaching, research, management). |
| MDT | A multidisciplinary team meeting is a joint team meeting. In most contexts it relates to a meeting that incorporates members of the colposcopy / histopathology / cytology units and involves discussion of mismatched cases. |
| PCT | Primary Care Trusts PCTs receive around 80% of the total NHS budget. They decide what health services a local community needs, and they are responsible for providing them. They must ensure that there are enough services for people within their local area, and that the services are accessible. PCTs make decisions about the type of services that hospitals provide and are responsible for making sure that the services are of sufficiently high quality. They purchase services from NHS Trusts . |

They make sure that NHS organisations work effectively with local authorities, and other agencies that provide local health and social care services, so that the local community's treatment needs are met.

LIMs

Laboratory Information Management Systems

Are information management systems designed specifically for the laboratory

The BSCC wishes to acknowledge the support of Dr Edward Duvall (Edinburgh), Ms Kathy Snee (Pathlinks laboratory Services) and Ms Caroline Burnley (North East & Yorks QARC) for their contributions to this document.