EXTERNAL QUALITY ASSESSMENT SCHEME FOR BREAST SCREENING HISTOPATHOLOGY

General Description and Standard Operating Procedures

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CONTENTS

PREFACE

The general description and standard operating procedures should be read in conjunction with *Standards for EQA Scheme Accreditation* published by Clinical Pathology Accreditation (UK) Ltd (CPA).[1] References to the appropriate paragraphs are indicated by EQA xx.

The general description and standard operating procedures were registered by CPA with effect from June 2003. This version incorporates subsequent changes to contact names and telephone numbers.

ACKNOWLEDGEMENTS

The scheme organiser would like to thank the Royal College of Pathologists' Steering Committee for External Quality Assessment in Histopathology and Cytopathology for assistance in preparing this scheme.

GENERAL DESCRIPTION OF EQA SCHEME (EQA 1A)

1	**Name**	NHS Breast Screening Programme (NHSBSP) Histopathology EQA Scheme.
2	**Geographical scope of scheme**	United Kingdom.
3	**Organiser of the scheme**	Dr Ian O Ellis Chairman of the National Coordinating Group for Breast Screening Pathology Department of Histopathology Nottingham City Hospital Hucknall Road Nottingham NG5 1PB Tel: 0115 9691169 (ext. 46875) Fax: 0115 9627768 Email: ian.ellis@nottingham.ac.uk
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5	**Technical administrator**	Miss Claire Paish Department of Histopathology Nottingham City Hospital Hucknall Road Nottingham NG5 1PB Tel: 0115 9691169 (ext. 46380) Fax: 0115 9627768
6	**Analysis and statistical support team**	Mrs Sandhya Kodikara, Dr Derek Coleman and Dr Sue Moss Institute of Cancer Research Cancer Screening Evaluation Unit Cotswold Road Sutton Surrey SM2 5NG Tel: 0208 7224191 Fax: 0208 7700802 Email: s.moss@icr.ac.uk

7 Introduction

The breast screening histopathology EQA scheme has three principal roles:

1. educational
2. mechanism for examination of concordance of pathology diagnosis within the UK
3. to provide a mechanism for individual performance appraisal.

The EQA scheme in breast pathology is of the 'consensus' variety as there is no prejudgement about the correct diagnosis, which is generally accepted to be that made by the majority of participants unless there is clear evidence to the contrary. This contrasts with the so-called 'proficiency testing' schemes in which the correct diagnoses are determined in advance by the organisers, who thus function similarly to examiners conducting an examination. Under the present system, the consensus data are derived from analysis of the coordinators' results. The coordinators are appointed on a regional basis as part of the NHSBSP quality assurance (QA) network. Additional coordinators include representatives from Scotland, Wales, Northern Ireland, Eire, the private sector and co-opted specialist breast pathologists.

Although the breast histopathology scheme is able to identify substandard performance, it also has significant educational value by allowing participants regularly to compare and discuss their diagnoses with other participants. Furthermore, not every case needs to be suitable for assessing performance and some rare and difficult lesions can be included. Unsuitable cases are simply identified by an inadequate level of agreement by the participants. Another advantage is that it allows valid studies of diagnostic consistency to be made as cases are selected in a random manner within diagnostic categories. Consistency studies undertaken during the first three years of the scheme have been published.

8 Categories of participants

Consultants, associate specialists and staff grade pathologists dealing with breast pathology:

category 1 – regional coordinators
category 2 – breast screening readers
category 3 – non-breast screening readers.

Trainees are encouraged to participate but are not allowed to submit results for analysis.

9 Organisation of scheme

The scheme is organised on a regional network basis mirroring the administrative network used by the NHSBSP. Each regional group has one, and in some of the larger regions two, coordinators who have contractual responsibility for provision of quality assurance within the NHSBSP. The regional coordinators are members of the National Coordinating Group for Breast Screening Pathology, which acts as the EQA scheme steering committee. The chairman of the National Coordinating Group is responsible for organising the EQA scheme.

Administration of regional circulation of EQA cases is the responsibility

of regional coordinators and is usually delegated to the regional breast screening quality assurance reference centre (QARC). Participants are classified as either breast screening readers or non-breast screening readers. The former group have contractual responsibility for provision of a breast screening pathology service within the UK NHSBSP. The latter group will have service commitments, which include provision of a breast pathology service outwith the NHSBSP.

10 Circulation of cases

Two circulations per year, each consisting of 12 cases.

Three sets of 12 slides are sent to each of the 17 regional coordinators on a six monthly basis. Currently, the coordinators represent the 14 former English health regions and the three Celtic nations. They distribute the slides to as many consultant pathologists as possible within their regions over a period of approximately four months. The number of slide sets issued to each region may vary according to the number of active participants in that region.

11 Responsibility for case preparation

This rests with the organiser and technical administrator. Responsibility for maintenance of participant records and code numbers, data collection and analysis rests with the secretariat and analysis and statistical support group.

12 Selection of cases

Cases are selected at random within broad diagnostic categories. All participants are eligible to submit cases. Requests for case submission are circulated through the regional network system, and participants are asked to identify a suitable case that they have reported in their practice in a period after a given date. In addition, requests are made specifically for examples of unusual or rare lesions of educational value or those selected to examine concordance of diagnosis amongst participants which would allow critical appraisal and improvement of the existing diagnostic criteria.

Clinical details and the original diagnosis are not requested.

13 Scoring of responses

Participants report the circulated sections using a standard form based on the NHSBSP pathology reporting form. The completed forms are sent to the Cancer Screening Evaluation Unit, where the data are coordinated and responses are analysed.

14 Determination of substandard performance

This is determined from four major diagnostic categories: benign (including radial scar), atypical hyperplasia, in situ carcinoma (including microinvasive) cases and invasive. Only those cases for which there is a majority diagnosis amongst the coordinators of at least 80% in any of these groups, and which are deemed appropriate at the coordinators' meeting, are included in the assessment. If the participant's diagnosis accords with the majority opinion, a score of 3 is given. A score of 2 is awarded if the diagnosis deviates by one group; 1 if it deviates by two groups; and 0 if it deviates by three groups. Thus, for a majority diagnosis of invasive carcinoma, scores of 3, 2, 1 and 0 would be awarded for diagnoses of invasive carcinoma, in situ carcinoma, atypical hyperplasia and benign respectively. Each participant's scores are then added together.

A participant is deemed to be a 'persistent substandard performer' if his/her total score for a circulation falls below the fifth percentile of the group (categories 1, 2 and 3) and remains below this level in one of a further two circulations. In every round, each participant is informed of their score and whether it is above or below the fifth percentile. The use of the fifth percentile to determine the cut-off point in practice usually identifies between 2% and 3% of participants falling below this level owing to the discrete nature of the scores.

Although trainees may participate in the scheme, their scores are not included in this assessment process. Only those participants (generally consultants) who take ultimate responsibility for their diagnoses in their normal practice will be assessed.

15 Release of results

The general analyses of consistency of diagnosis and reporting prognostic features on individual cases are sent to all participants, who are thus able to see the spread of opinions on each case and how theirs relate to those of the majority. There is evidence that this process improves diagnostic consistency. The secretary in the Cancer Screening Evaluation Unit links participants' codes to their names and addresses so that the scheme organiser and other members of the Cancer Screening Evaluation Unit are unaware of individual participants' opinions.

16 Definition of participation

It is unreasonable to expect all participants to take part in each circulation, and participation is thus defined as taking part in two out of every three circulations. Given the large size of the scheme and the occasional logistical difficulties of reaching all participants this definition may rarely have to be relaxed. A certificate of participation is issued where required to those who fulfil this criterion. Given that all those taking part in the scheme will regularly be reporting breast specimens, and cases are included for scoring only where the majority opinion is made by 80% of coordinators, it is not acceptable for participants to omit any cases.

17 Action to be taken on identifying a substandard performer

The principal aim of the scheme is educational, providing participants with personal feedback on concordance of their diagnoses of breast screening cases with a large peer group of histopathologists.

It should be stressed that external quality assessment schemes are a convenient but artificial mechanism for auditing the performance of histopathologists. There are several reasons why the standard achieved in a scheme may not reflect performance in daily diagnostic practice. Knowing that no clinical action will follow the reporting of the EQA slides, some participants devote little effort to them, whereas others may spend a disproportionately long time for fear of being deemed substandard. Only one slide per case is circulated in the EQA scheme and no clinical data are provided. There are no opportunities to undertake further investigations or express uncertainty.

The main control points are described fully in SOP10, but the key action points are described in outline below.

The definition of a 'persistent substandard performance' will be when a participant's total score for a circulation falls below the fifth percentile of the whole group and remains below this level in one of the next two circulations. Should such an event occur the participant will be informed by the scheme organiser via the secretariat. Should the participant's score fall below the fifth percentile in two of the next three circulations, the EQA secretary informs the organiser, who informs the chairman of the Histopathology/Cytopathology National Advisory Panel of the Joint Working Group on Quality Assurance. The organiser will not have been informed of the identity of the participant, but the chairman of the Advisory Panel is entitled to be informed of the identity of the participant by the EQA secretary.

This description is accurate at the time of writing. The operation of the scheme is under continual review and may change in the light of experience and future developments.

18 Financial aspects

This is a non-profit making scheme. The scheme is funded directly by the NHSBSP and no charges are levied for participation. The organisers' costs are reviewed on an annual basis.

19 Sample of feedback to participants

Refer to Appendix.

STANDARD OPERATING PROCEDURES

STANDARD OPERATING PROCEDURE 1

Maintenance of standard operating procedures (EQA 1F)

Standard operating procedures (SOPs) are kept in paper form in a loose folder in the office of the EQA scheme organiser. Before submission of the report of the EQA Steering Committee to the National Coordinating Group for Breast Screening Pathology, each SOP is reviewed by the organiser, signed and dated.

If it is necessary to amend an SOP or create a new one, this is done by the organiser in draft form. This amendment is circulated to regional coordinators for their approval and the new and old forms are submitted to the National Coordinating Group along with the annual report with a request for approval. Amendments can be used pending approval via the Steering Committee. Each SOP is marked with the date of approval by the National Coordinating Group.

Signed _____ (Scheme organiser)

Dated _____

STANDARD OPERATING PROCEDURE 2

Scheme membership (EQA 11)

The scheme is mandatory for pathologists reporting histology specimens generated by the NHSBSP and is available to other pathologists providing a symptomatic breast pathology service. These participants are independent practitioners, ie consultant, staff grade and associate specialists who have the authority to report independently on such material. Some independent practitioners who report histological specimens from symptomatic breast practice or from patients undergoing treatment following a diagnosis made by screening are also eligible to participate, but are recognised as non-screening readers. Trainee specialist registrars are encouraged to participate in the scheme but may not submit results for analysis and will not be subject to action for persistent poor performance.

When a participant is away from work for a protracted period (eg sabbatical, maternity leave or illness) then he/she should inform the regional organiser and their participation can be suspended.

Signed _____ (Scheme organiser)

Dated _____

STANDARD OPERATING PROCEDURE 3

Enrolment and new participants (EQA 3B)

An individual taking up post as an independent practitioner responsible for histological reporting of breast screening cases will be made aware by their regional NHSBSP QA network that participation in the scheme is required and individuals should register directly with the scheme secretariat.

On receiving notification, the scheme secretariat will record the new participant's details and issue the individual with a unique code number. Details of participant's code numbers are held at the secretariat office and are not disclosed to the scheme organiser or other participants of the scheme. New participants will be sent a brief description of the scheme, asked to read it and confirm that he/she wishes to participate on those terms.

The scheme is conducted on an anonymised basis, each participant being issued with a personal numerical code. Participants' names, addresses and codes are held on a secure computer system at the secretariat.

Signed _____ (Scheme organiser)

Dated _____

STANDARD OPERATING PROCEDURE 4

Obtaining case material (EQA 2B, 4A–H)

Cases for circulation in the EQA scheme are provided by the participants in rotation. The submitting participating laboratories should participate in a technical EQA scheme and have full or conditional CPA approval.

At the organiser's discretion, an appropriate number of letters are sent to participants, selected on the basis of an alphabetical rotation and within each regional group. These letters request the provision of two cases for the EQA scheme. A representative paraffin block suitable for preparation of up to 70 histological sections is required. The participant is asked to select one suitable case from his/her routine breast screening pathology practice in a period of one month following a given date. The participant is also asked to provide a case which would be of interest as a good example, a rare lesion or an educational lesion. In view of the nature of the scheme, participants are not routinely requested to provide a proffered diagnosis, clinical or additional pathology information.

The submitting pathologist is asked to check whether the material is of adequate quality. The organiser at present confirms the quality of the material prior to entry of a given case into the scheme.

On receipt of the case, the organiser enters the relevant information into the appropriate part of the participant's address management database, thereby cancelling the request for a case. The case will be assigned an appropriate registration number. Prior to each circulation, the organiser examines the submitted cases in sequence and accepts cases in order for use in the scheme. Unsuitable cases are removed and not circulated.

Signed _____ (Scheme organiser)

Dated _____

STANDARD OPERATING PROCEDURE 5

Initiating and maintaining the circulation (EQA 3C)

Prior to the start of a new circulation, sufficient response sheets are printed to supply each participant with one copy per case. Submitted cases are reviewed in a consecutive order by the organiser and accepted for circulation. Occasionally, cases are rejected for reasons such as poor tissue preservation or insufficient tissue remaining in the block, or they are deferred for later circulations to ensure a reasonable case mix for each circulation. The selected cases are again reviewed by the organiser following preparation of the sections. Approximately 60 slides will have been cut from each block; the 1st, the 30th and the 60th are reviewed by the organiser to confirm that the lesion is represented throughout the circulated material and to measure any variation in tumour size or other characteristics.

Appropriate numbers of case sets, usually three, are sent to each regional coordinator with an appropriate number of response forms. The regional coordinators arrange circulation of the slide sets among participants in their region. Typically, the coordinators will send response sheets to each participant with a circulation list indicating the date when the slide set should be received and the date when it should be sent to the next participant on the list. The circulation of slide sets can be monitored by regional quality assurance office staff. Each participant is responsible for completing their response sheets to include their code numbers, and they are responsible for sending their response sheets directly to the secretariat within the given deadlines.

Signed _____ (Scheme organiser)

Dated _____

STANDARD OPERATING PROCEDURE 6

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

Participants receive a confidential numeric code which is generated by the EQA secretariat. The secretariat maintains a list of EQA scheme participants. The list forms part of a database, which is held on computer within the host organisation's network. Access to the network is restricted to registered users, who can only see areas pertaining to them. Each user requires a unique password to access the network. The database itself can only be accessed by the scheme secretariat and is password protected. Passwords are changed at regular intervals. The database password is known to the scheme secretariat only. This database is the only link between the participants' codes and their personal details. It is not made available to the scheme organiser or to other participants.

The scheme organiser communicates with participants, who are identified only by their code number, through the scheme secretary. Any confidential material from the organiser is passed to the scheme secretary with only the relevant code number exposed, such that the communication is placed in an appropriately addressed envelope by the EQA scheme secretary without the secretary having to read the contents of the communication.

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

1. In writing (postal or email) to a participant who requests a reminder of his/her code number. Code numbers must not be divulged by telephone or fax.
2. The name and details of participation results in writing to the Chairman of the Histopathology/Cytopathology Advisory Panel of the Joint Working Group on Quality Assurance, only when justified by SOP 11, in order to investigate appropriately a case of persistent substandard performance in the EQA scheme.
   No EQA result may be divulged to any other authority – see Executive Letter EL98/2.[2]

Signed _____ (Scheme organiser)

Dated _____

STANDARD OPERATING PROCEDURE 7

Receipt and analysis of EQA responses (EQA 3)

Responses in the EQA scheme are returned by participants bearing their confidential code number and name to the EQA secretariat. The scheme secretary should record receipt and date stamp each set of responses. These sheets are entered into a database using an automated scan reading system. A back-up of computer records should be kept off site in case of fire. The participants are recognised by their individual code numbers. Responses are requested to be received by one of two closing dates. The first is for the EQA scheme organiser and regional coordinators and is prior to a meeting of the National Coordinating Group, at which submitted results of each case are discussed and individual case eligibility is recorded.

Responses received by the second date are included in the final analysis. Results for each case are circulated to participants via the regional coordinator network. Personal performance appraisal is carried out for cases deemed eligible following the meeting of the National Coordinating Group.

The analysis consists of a set of standard tables agreed at the meetings of the regional coordinators. They tabulate the classification for each case and, where appropriate, give the kappa statistic for each diagnosis.

Signed _____ (Scheme organiser)

Dated _____

STANDARD OPERATING PROCEDURE 8

The participants' meetings (EQA 1H)

A meeting of the National Coordinating Group takes place following the first closing date for each circulation. The analysis of the regional coordinators' results, and that of any participating pathologist who has submitted a result by that date, is available for discussion. Classification for each case is reviewed, and the agreed diagnosis and classification are recorded. Eligibility for personal performance appraisal is agreed for each case acquiring a majority diagnosis of at least 80% of the coordinators, but this may be waived in exceptional circumstances following discussion.

Following release of the analysed results to all participants, participants are invited to attend a regional meeting chaired by each regional coordinator. Circulated cases are reviewed and discussed. The regional coordinator should have attended the National Coordinating Group meeting and will have been provided with a summary of the agreed diagnosis and classification of each case. Feedback from individual participants is conveyed to the National Coordinating Group via the regional coordinator.

Signed _____ (Scheme organiser)

Dated _____

STANDARD OPERATING PROCEDURE 9

Feedback to participants (EQA 2G, EQA 3D)

After the meeting of the National Coordinating Group, the scheme secretariat notes those cases that have been excluded and those eligible for inclusion, as instructed by the National Coordinating Group.

The results of all participants and a full list of all participants' personal performances are printed and sent to regional coordinators for circulation to all participants.

It is anticipated that, in the future, after the individual scores have been calculated, the secretariat will check the database to test whether any of the participants fulfil the criteria for persistent substandard performance.

This is determined from four major diagnostic categories: benign (including radial scar), atypical hyperplasia, in situ carcinoma and invasive. Cases where there is a majority diagnosis of at least 80% in any of these groups are included in the assessment. If the participant's diagnosis accords with the majority opinion, a score of 3 is given. A score of 2 is awarded if the diagnosis deviates by one group, 1 if it deviates by two groups and 0 if it deviates by three groups. Thus, for a majority diagnosis of invasive carcinoma, scores of 3, 2, 1 and 0 would be awarded for diagnoses of invasive carcinoma, in situ carcinoma, atypical hyperplasia and benign, respectively. Each participant's scores are then added together. A participant is deemed to be a 'persistent substandard performer' if his/her total score for a circulation falls below the fifth percentile of the group (categories 1, 2 and 3) and remains below this level for one of the next two circulations. The use of the fifth percentile to determine the cut-off point in practice usually identifies between 2% and 3% of participants falling below the level owing to the discrete nature of the scores. In every round, each participant is informed of their score, providing participants with personal feedback on concordance of their diagnoses of breast screening cases with a large peer group of histopathologists and whether it is above or below the fifth percentile.

Although trainees may participate in the scheme, their scores are not included in this assessment process. Only those participants (generally consultants) who take ultimate responsibility for their diagnoses in their normal practice will be assessed.

Participation in the scheme is notified to regional coordinators and QARC staff.

Signed _____ (Scheme organiser)

Dated _____

STANDARD OPERATING PROCEDURE 10

Persistent substandard performance (EQA 1G, EQA 2E, 2F)

After the calculation of personal scores for each circulation, the database places the individual participant's scores for that circulation in rank order. A participant is deemed to be a 'persistent substandard performer' if their total score for a circulation falls below the fifth percentile of the whole group and remains below this level in one of the next two circulations. In every round, each participant is informed of their score and whether it is above or below the fifth percentile.

The secretariat checks whether any participant whose score falls within this range has also had a score fall within this range in either of the preceding two circulations. If such a participant is found, the organiser is notified and sends a 'Dear Colleague' letter to that participant, pointing out the position, offering appropriate sources of advice and assistance and informing the participant that, if the score results in a similar ranking in two out of the next three circulations, the chairman of the Advisory Panel will have to be asked to investigate. It should also be made clear that, for the next three circulations, a failure to participate will be considered equivalent to a score below the fifth percentile. This letter is identified by the participant's number only, and is passed to the EQA secretary in a sealed envelope for posting to the relevant participant.

The participant is asked to confirm that this letter has been received, by reply through the EQA secretary bearing no identifying marks other than the participant's code number. If such a reply is not received within three weeks, the secretariat sends a reminder; if a reply is not received within another four weeks, the secretariat informs the organiser, who informs the Advisory Panel chairman of the position.

The event of such a letter having been sent is recorded in the database. If such a participant's score again falls below the fifth percentile in two of the next three circulations, the EQA secretary informs the organiser of this event, who informs in writing the chairman of the Advisory Panel. It is anticipated that the chairman of the Advisory Panel will investigate the matter, initially without knowing the participant's name, communicating through the EQA secretary. Subsequently, however, the chairman of the Advisory Panel is entitled to be informed of the identity of the relevant participant by the EQA secretary. At no time should the scheme organiser be informed of the identity of any participant under such investigation.

This EQA scheme does not use the concept of 'dangerous diagnoses' as a criterion for defining substandard performance. When writing to the participant pointing out persistent substandard performance, or when communicating with the Advisory Panel chairman, the EQA scheme secretariat uses the database to print a listing that is as complete as possible of all diagnoses made by the participant in question, and this list

should be provided to the participant and the Panel chairman. Copies of the EQA material for cases on this list should be made available on request to the participant or the Panel chairman.

If the organiser becomes concerned that the performance of a participant gives cause for concern, such that the quality of patient care may be in doubt, the organiser is entitled to bring this to the attention of the Advisory Panel chairman even if the above numeric criteria have not been fulfilled. In this event, the organiser should, if possible, first present data relating to the participant's performance in an anonymous form at a National Coordinating Group meeting. That meeting should be invited to decide whether the Advisory Panel chairman should be informed.

The above procedures do not replace or alter in any way the obligation placed by the General Medical Council upon the organiser, as a doctor, to take appropriate action to protect patient care if the organiser believes that patient care is put at risk.

Signed _____ (Scheme organiser)

Dated _____

STANDARD OPERATING PROCEDURE 11

Communications and complaints (EQA 3H, 3I)

All written communications from participants to the organiser or the secretary will be stored in a file for a minimum of four years.

Where a telephone or verbal communication is made, the organiser or secretary receiving the communication will make a written note summarising the communication and that will be dated and stored in the same file.

Where the communication may be construed as a complaint, the action taken to remedy the complaint will be recorded and dated, clipped to the original communication in the file.

If the organiser judges the complaint to be justified and of a nature which requires any alteration in the procedures of the scheme, the preferred sequence of events for enacting such changes would be in accordance with SOP1:

1. discussion at the participants' meeting
2. production of a draft revision to the relevant SOP
3. implementation, pending approval by the National Coordinating Group
4. notification of the revision by the National Coordinating Group

If the organiser deems that a change in procedure is too urgent to permit such discussion, a revised SOP may be generated and implemented immediately, for subsequent discussion at the participants' meeting and National Coordinating Group as laid out in SOP1.

In the unlikely event of a complaint being handled locally to the dissatisfaction of a participant, the participant can complain direct to the Chairman of the Royal College of Pathologists' Steering Committee for EQA in Histopathology/Cytopathology.

Signed _____ (Scheme organiser)

Dated _____

STANDARD OPERATING PROCEDURE 12

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

Comments on the mode of operation of the scheme are invited at every regional participants' meeting. Changes proposed at such meetings will normally be reviewed by the National Coordinating Group, as below (SOP1). Suggestions for a change of the scheme organiser should be discussed first at this meeting; such suggestions must be considered if made by any scheme member. As far as possible, decisions at the participants' and National Coordinating Group meetings should be made on a democratic basis of those present.

A report is provided annually to the National Coordinating Group for Breast Screening Pathology, the Royal College of Pathologists' Steering Committee for EQA in Histopathology/Cytopathology and to the National Quality Assurance Advisory Panel (NQAAP) on the work of the scheme, with particular emphasis on any changes in how the scheme runs, either actual or planned. Specifically, any changes in these SOPs must be communicated to the National Coordinating Group for approval, as documented in SOP1.

The annual report provided to the National Coordinating Group must also include any changes in the assessment procedure and in procedures for managing substandard performance, either actual or planned, and also the number of participants who triggered action in response to substandard performance in the previous year.

Signed _____ (Scheme organiser)

Dated _____

STANDARD OPERATING PROCEDURE 13

Host organisation (EQA 1B)

The scheme operates from within the following organisation: organiser and technical administrator based at the Department of Histopathology, Nottingham City Hospital, Hucknall Road, Nottingham NG5 1PB.

Secretariat and data analysts based at the Cancer Screening Evaluation Unit, Institute of Cancer Research, Cotswold Road, Sutton, Surrey SM2 5NG.

Signed _____ (Scheme organiser)

Dated _____

STANDARD OPERATING PROCEDURE 14

Finance (EQA 1C, 1D, EQA GL3)

The cost of running the scheme and its supervision is covered by the NHSBSP. This funding covers the costs incurred by the organiser with respect to technical preparation, postage, stationery and staff time. The organiser provides the NHSBSP national office with their estimated costs on an annual basis prior to the forthcoming financial year.

Signed _____ (Scheme organiser)

Dated _____

STANDARD OPERATING PROCEDURE 15

Accounting (EQA1C, 1D)

The organiser's costs are managed by the Department of Finance, Nottingham City Hospital, Hucknall Road, Nottingham NG5 1PB.

Signed _____ (Scheme organiser)

Dated _____

STANDARD OPERATING PROCEDURE 16

Staffing (EQA 1E, 1C, EQA GL1A)

Organiser of the scheme

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Signed _____ (Scheme organiser)

Dated _____

STANDARD OPERATING PROCEDURE 17

Training (EQA GL4B)

There is no specific training for work on the EQA scheme; problems are resolved by informal discussion between the organiser, secretariat and the technical administrator. Should training need to be identified, then the organiser will arrange for appropriate training sessions as required. The organiser participates in continuing medical education, which is monitored by the Royal College of Pathologists.

Signed _____ (scheme organiser)

Dated _____

REFERENCES

1. *Standards for EQA Scheme Accreditation.* Sheffield, Clinical Pathology Accreditation (UK) Ltd, 1998.
2. *EL(98)2: Oversight of Provision of External Quality Assessment Schemes in Histopathology, Cytopathology, Cytogenetics and Molecular Genetics for Pathology Laboratories.* London, Department of Health, 1998.

APPENDIX

Sample of feedback to participants

Extracted from second analysis (forms received up to 26/02/2001) of circulation 2000/2 (466 pathologists).

Table 1 Distribution of individual opinions on each case

Case (no of pathologists if < 466)		Benign	Atypical hyperplasia	In situ or microinvasive	Invasive	% of readers in agreement with coordinators' majority diagnosis
13	(464)	0	1	461	2	99
14		0	0	0	466	100
15		440	25	0	1	94
16	(458)	90	57	68	243	53
17	(434)	154	7	1	272	63
18	(465)	0	0	0	465	100
19		1	2		459	98
20		3	9	450	4	97
21		0	0	0	466	100
22	(465)	1	0	430	34	92
23		8	21	10	427	92
24	(463)	0	0	0	463	100
	5545	697	122	1424	3302	91
Kappa						Overall kappa
4 categories		0.66	0.06	0.88	0.78	0.76
2 categories (benign/malignant)			0.65			0.65

Table 2 Architecture of invasive cancers

For each case, there can be two rows: ST and MIX. ST counts the number of pathologists who considered the case to be either no special type or one of the pure special type components. MIX counts the components when pathologists considered it to occur as a mixture.

Case		NST	Tubular	Lobular	Mucinous	Medullary	Papillary	Other	
14	ST	19	0	424	0	0	0	0	
	MIX	18	1	22	0	0	0	0	
16	ST	72	88	0	0	0	10	52[1]	
	MIX	11	13	0	0	0	7	2	
17	ST	0	0	0	0	0	0	268[2]	
18	ST	0	0	1	463	0	0	0	
19	ST	247	94	14	0	0	0	0	
	MIX	23	86	70	0	0	0	0	
21	ST	213	1	218	0	0	1	19[3]	
	MIX	6	0	5	0	0	0	1	
23	ST	255	146	0	0	0	0	1	
	MIX	8	6	1	0	0	0	3	
24	ST	412	14	0	0	0	1	5	
	MIX	3	3	0	0	0	0	0	
Kappa									Overall kappa
	ST	0.47	0.27	0.72	1.00		0.04	na	0.61
	MIX	0.12	0.11	0.10	0.10		0.11		Not applicable

1 Secretory carcinoma (36 pathologists), adenoid cystic carcinoma (9), malignant adenomyoepithelia (1), metastatic carcinoma (1), apocrine carcinoma (1), not specified (4).

2 Leiomyosarcoma (145), sarcoma (61), spindle cell carcinoma (22), metaplastic carcinoma (15), carcinosarcoma (6), stromal sarcoma (6), phyllodes tumour (5), not specified (2).

3 Neuroendocrine/endocrine carcinoma (10), possible carcinoid tumour (6), argyrophil carcinoma (1), malignant adenomyoepithelioma (1), not specified (1).

Table 3 Grade of invasive cancers

Case	Grade 1	Grade 2	Grade 3	Not entered/not assessable
14	78	347	10	31
16	183	35	0	25
17	1	6	9	256
18	360	57	0	48
19	416	10	0	33
21 (NST)	138	291	5	32
23	377	14	2	34
24 (NST)	70	313	64	16
Total	1623	1073	90	475
Kappa				Overall kappa
On all cases	0.52	0.45	0.09	0.46

The NST cases are determined by the coordinators' consensus, which differs from all pathologists in this circulation.
Case 17 has been excluded from the kappa calculations in all the grade tables (Tables 3 to 6).
Kappa statistics on NST cases are not presented because the majority opinion was the same for both cases; under these circumstances, kappa statistics are misleadingly low.

Table 4 Tubules component of grade

Case	Overall grade (% agreement)	Grade 1	2	3	
14	2 (80%)	2	9	380	
16	1 (84%)	144	55	7	
17	na	0	0	9	
18	1 (86%)	65	235	92	
19	1 (98%)	165	216	15	
21 (NST)	2 (67%)	3	24	379	
23	1 (96%)	357	15	6	
24 (NST)	2 (70%)	281	129	11	
Total		1017	683	899	
Kappa					Overall kappa
On NST cases		0.48	0.10	0.83	0.53
On all cases		0.49	0.27	0.75	0.52

Table 5 Pleomorphism component of grade

Case	Overall grade (% agreement)	Grade 1	2	3	
14	2 (80%)	81	29	13	
16	1 (84%)	30	46	30	
17	na	0	0	9	
18	1 (86%)	208	181	2	
19	1 (98%)	320	75	1	
21 (NST)	2 (67%)	111	259	7	
23	1 (96%)	71	261	45	
24 (NST)	2 (70%)	3	134	283	
Total		854	1354	390	
Kappa					Overall kappa
On NST cases		0.20	0.10	0.47	0.26
On all cases		0.30	0.17	0.44	0.27

Table 6 Mitotic score component of grade

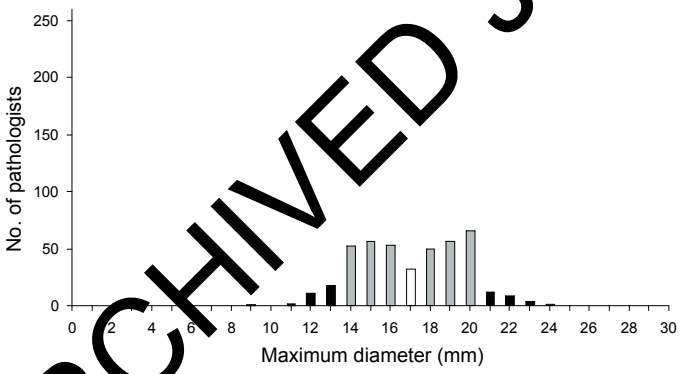
Case	Overall grade (% agreement)	Grade 1	2	3	
14	2 (80%)	355	29	8	
16	1 (84%)	194	12	0	
17	na	4	2	3	
18	1 (86%)	386	5	0	
19	1 (98%)	388	2	1	
21 (NST)	2 (67%)	365	40	1	
23	1 (96%)	365	9	0	
24 (NST)	2 (70%)	48	185	186	
Total		2105	284	199	
Kappa					Overall kappa
On NST cases		0.61	0.15	0.28	0.37
On all cases		0.64	0.23	0.37	0.45

Table 7 Vascular invasion of invasive cancers

Case	Vascular invasion	
	Not seen	Present
14	414	16
16	213	1
17	161	0
18	404	9
19	394	0
21	393	32
23	278	106
24	393	15
Total	2650	179
Kappa	0.13	0.13
Overall kappa	0.13	

Size of invasive lesions (mm)

Case No. 14



Case No. 16

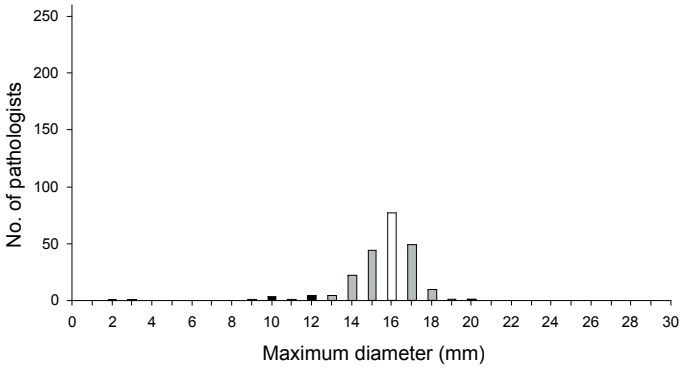


Table 8 Non-invasive lesions – nuclear grade of ductal cases

Case	Nuclear grade High	Intermediate	Low	Not entered
13	425	28	1	1
20	25	232	184	4
22	99	294	26	5
	549	554	211	10
Kappa				Overall kappa
3 categories	0.60	0.30	0.25	0.41
2 categories (High/other)	0.60	0.60		0.60

Size of non-invasive lesions (mm)

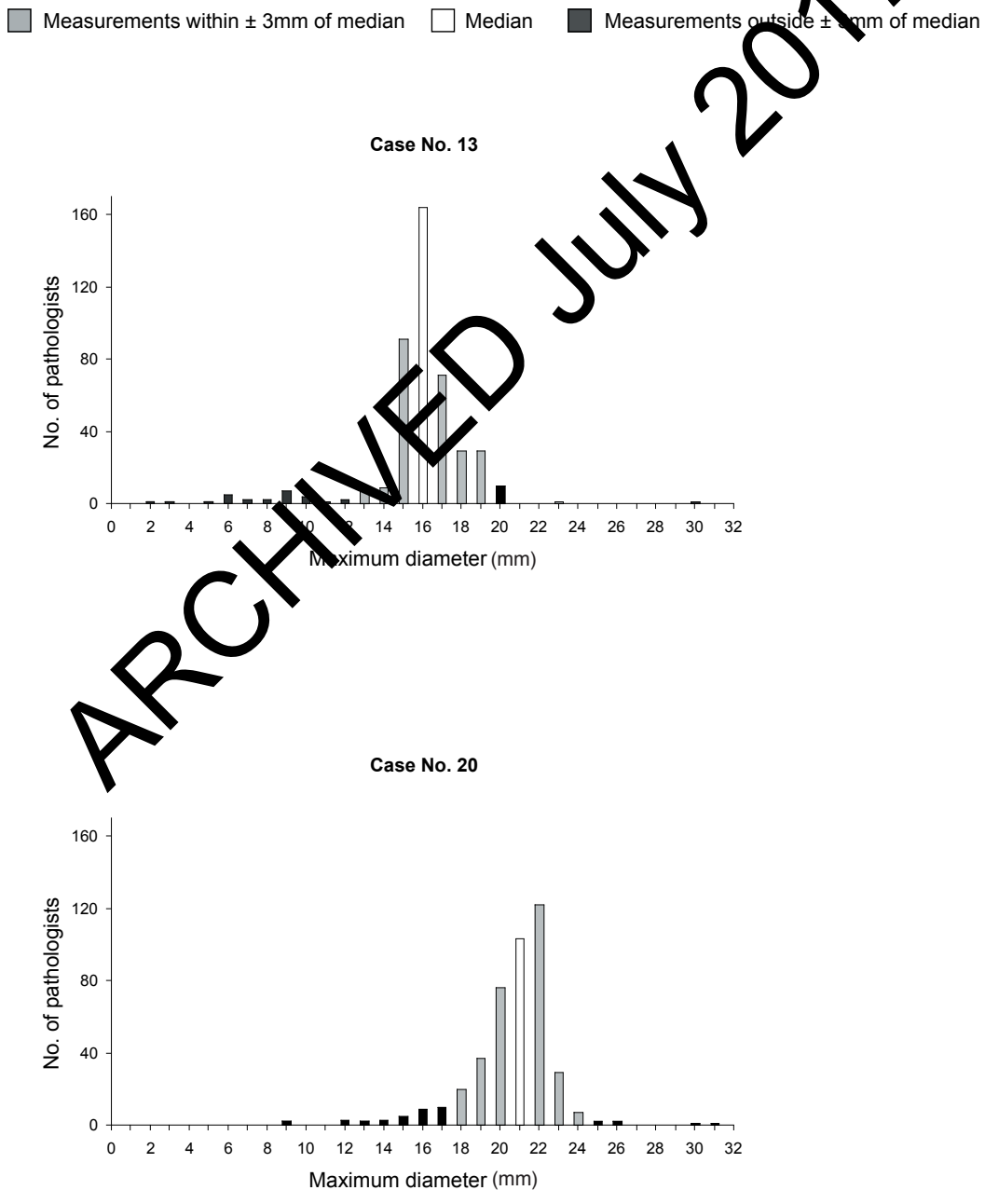


Table 9 Regional statistics on all cases

QA region	No of readers	% agreement with coordinators' consensus	Kappa statistic for current circulation	Kappa statistic for previous four circulations
Northern and Yorkshire	23	89	0.77	0.83
Trent	32	92	0.79	0.84
West Midlands	21	91	0.80	0.82
North West	32	92	0.76	0.81
Eastern	43	88	0.70	0.80
London	57	91	0.75	0.80
South East	86	92	0.77	0.83
South West	42	91	0.76	0.79
Wales	10	92	0.83	0.78
Scotland	22	94	0.84	0.83
Northern Ireland	24	92	0.80	0.82
All NHSBSP pathologists	392	91	0.77	0.81
Non-screening pathologists	72	90	0.74	0.81
Regional coordinators	22	91	0.77	0.85
All pathologists	466	91	0.76	0.81

Table 10 Statistics for individual pathologists

The second and fourth column shows the individual pathologist's overall diagnosis for each case, depending on whether it was included or excluded from the measure of agreement. Each pathologist's diagnoses are concatenated together in their numerical order using the following abbreviations:

B benign
A atypical hyperplasia
S in situ or microinvasive
I invasive
x no reading was submitted
o omitted from measure of agreement

Pathologist	Diagnoses of cases included in measure of agreement	Measure of agreement (%)	Diagnoses of cases excluded from measure of agreement
Coordinator's consensus	SIBooIISISII		II
X	SIBooIISISII	100	IB
X	SIBooIISISII	100	II
X	SIBooIISISII	100	BI
X	SIBooIISIIII	97	II
X	SIBooIISISII	100	Bx
X	SIBooIISISII	100	AI
X	SIBooIISISII	100	II
X	SIBooIISISII	100	II
X	SIBooIIIISII	97	II
X	SIBooIISISII	100	BI
X	SIBooIISISII	100	BI
X	SIBooIISISII	100	SI
X	SIBooIISISII	100	SI

Table 11 Distribution of measure of agreement for NHSBSP pathologists

Measure of agreement (%)	No of pathologists	Cumulative no of pathologists	Cumulative percentage
91	2	2	0.5
94	9	11	2.8
97	46	57	14.5
100	335	392	100.0