GUIDANCE NOTES FOR EQUIPMENT EVALUATION: PROTOCOL FOR USER EVALUATION OF IMAGING EQUIPMENT FOR MAMMOGRAPHIC SCREENING AND ASSESSMENT

NHSBSP Equipment Report 0703
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CONTENTS

This publication was archived on 05 August 2016

This publication was archived on 05 August 2016

PREFACE

This is the second revision of these guidance notes and supersedes the previous version published in October 2002 as NHSBSP Publication No 51. The guidance now includes protocols for the evaluation of digital equipment and guidance on writing evaluation reports.

The guidance notes have been revised by the NHSBSP Equipment Group with help and advice from the following:

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This publication was archived on 05 August 2016

1. INTRODUCTION

The evaluation of mammographic x-ray equipment used in the NHS Breast Screening Programme (NHSBSP) is carried out in centres where the staff routinely perform screening and assessment examinations of women. Evaluations are undertaken to assess the practical use of equipment and are not intended to be clinical trials.

Currently, a number of breast screening centres in England undertake the evaluation of equipment using the protocols provided by the NHSBSP. These evaluations are staged processes that start with a technical evaluation. Measurements for the technical evaluation may be made by the NHS Purchasing and Supply Agency (PASA) Centre for Evidence-based Purchasing (CEP) (subject to a successful project appraisal and agreement by the CEP Prioritisation Board), by the local mammography physics service, by the National Coordinating Centre for the Physics of Mammography (NCCPM), or by a combination of these. The centre may proceed with the clinical evaluation only after a satisfactory technical evaluation and with the agreement of the NHSBSP national office.

The reports of completed evaluations are published by the NHS Cancer Screening Programmes. They are intended to:

- determine the suitability of equipment for use within the NHSBSP
- assist potential purchasers in making their choice of equipment
- provide potential users with performance data about equipment.

Because consistent performance standards are used for any particular type of equipment, comparisons can be made by studying several reports.

Technical reports comparing several systems have been published by the CEP. They can be found at http://www.pasa.nhs.uk

This publication was archived on 05 August 2016

2. SELECTION OF EQUIPMENT FOR EVALUATION

Equipment for possible evaluation in the NHSBSP should be brought to the notice of the national office representative on the NHSBSP Equipment Group. The national office will undertake all necessary discussions and decide on the appropriateness of proceeding to a clinical evaluation. Reports will be made to the NHSBSP Equipment Group on the progress of evaluations.

This publication was archived on 05 August 2016

3. SELECTION OF EVALUATION CENTRES

3.1 Eligibility criteria for evaluation centres

Breast screening centres taking part in the evaluation programme must fulfil the following criteria to ensure that they are able to provide the appropriate level of expertise and sufficient throughput of women for screening mammography. Centres may be suitable for the evaluation of some systems but not others.

- The mammography machine under evaluation should not be the only x-ray machine available to the centre. This prevents difficulties that may result from time lost for installation, training, familiarisation and technical problems.
- The breast screening centre selected for the evaluation should have sufficient throughput for the period of the evaluation and a robust quality assurance system that meets all relevant NHSBSP objectives and technical guidelines.
- For film-screen equipment, an established and stable film processing system with dedicated processing facilities is an essential requirement and should be used throughout the evaluation. In addition, a set of good quality matched cassettes/intensifying screens should be available for the evaluation.
- For digital machines (either computerised radiography (CR) or direct digital radiography (DR)), there must be a robust system in place for image archiving and retrieval. If the equipment is on loan for the evaluation, there must be clear arrangements for the archives to remain accessible.
- The local mammography physics service, radiographers and radiologists involved in the evaluation should all comply with the relevant NHSBSP professional guidelines.
- Mammography screening machines may require evaluation when mounted in trailers. This should be carried out after the machine (or a similar type of machine) has been fully evaluated at a static site.

3.2 Service level agreements

A service agreement between the NHSBSP and the evaluation centre is required because a contribution towards the costs of the evaluation is funded by the NHSBSP. Copies of a service level agreement are given in Appendix 1 for film-screen systems and Appendix 2 for digital systems. The centre undertaking the evaluation is responsible for dissemination of the funding to the various internal groups and outside agencies involved in installation, safety and performance checks, clinical use and evaluation, collation of data and writing the report of the clinical evaluation.

3.3 Project management

A project leader should be appointed by the centre to coordinate the evaluation, to ensure that all required areas are covered and to ensure that there is effective liaison between the screening centre, the supplier/manufacturer/installer and the NHSBSP representatives. Timescales should be established and agreed as soon as availability of the equipment is confirmed. A staged approach should be taken starting with the technical evaluation. The project should progress to the clinical evaluation only if the technical evaluation is satisfactory.

3.4 Trust awareness of the evaluation

If the equipment is borrowed from the supplier for the period of the evaluation only, it is important to have an agreement with the supplier and the host trust for costs and liability. A local agreement should be formally made between the supplier and the host trust. Some trusts may require the evaluation project to have agreement from the ethics committee or novel procedures committee.

This publication was archived on 05 August 2016

4. WORKLOAD AND EVALUATION PERIOD

4.1 Throughput

The workload at the evaluation site should mirror the standard working practice at a screening centre or assessment centre as appropriate. Levels of throughput are suggested but may need to be tailored for the equipment under evaluation. It is important to assess whether existing throughput can be maintained or whether it could be increased using the equipment under evaluation, eg by applying non-standard appointment times to some clinics. All evaluations should pay particular attention to any novel design features or modes of operation of the machine which may affect throughput.

4.2 Evaluation period

The evaluation period (not including installation and technical acceptance testing) should be for a minimum of 3 months but usually not more than 6 months. This should provide an indication of long term reliability and consistency of performance. A longer time period may be necessary for new technology, systems suffering from frequent downtime or inconsistency in performance.

4.3 Evaluation of x-ray machines for mammography screening

Evaluators of mammography screening machines should aim to examine at least 500 women on the machine during the period of the evaluation in order to highlight any operational defects or shortcomings in performance. A full range of breast sizes should be covered, including larger and denser breasts. In the case of digital equipment, women with breast implants should be included.

Once the machine has reached full and acceptable operational status, a number of full screening sessions (a minimum of eight is suggested) should be arranged, with at least 50 women examined over a working day. Such workloads should not prove a problem at screening centres, but special arrangements may have to be made if the evaluation is performed at a centre that is primarily used for assessment. It is important to establish that the equipment is able to work effectively in the NHSBSP and is acceptable from both user and client perspectives.

The evaluation centre should record at least two clinics' worth of information.

4.4 Evaluation of x-ray machines in an assessment setting

The evaluators should aim to examine at least 200 women on an assessment machine, although at larger or busier centres the number may be considerably higher. All modes of operation of the machine should be evaluated, including magnification and stereotactic operation if applicable. For the latter, both adaptation of the equipment to stereotactic use and operation of the equipment in the stereotactic mode should be examined. In the event that a full evaluation of the stereotactic device is required, this will be the subject of separate protocols and addressed within the service agreement.

The minimum workload should be at least 25 magnification examinations and 10 stereotactic examinations. The evaluation period should be similar to those for screening machines. As with screening machines, the evaluation should cover a full range of breast sizes and densities.

This publication was archived on 05 August 2016

4.5 Evaluation of other types of equipment for mammography

There may be a requirement to evaluate other types of mammography x-ray machine, such as prone biopsy systems and specimen x-ray systems. Clear objectives for these evaluations will be decided between the national office and the evaluation centre.

4.6 Evaluation of computerised radiography systems

Computerised radiography (CR) systems designed for mammography will be considered for evaluation only if they are capable of meeting current NHSBSP standards.[1] The decision as to which should be evaluated will be made following discussions with the national office and the supplier. Any x-ray equipment used with the CR system must itself operate within NHSBSP standards and must be compatible with the CR system to ensure optimisation can be achieved.

4.7 Early termination of an evaluation

If equipment is unreliable or there are concerns about the consistency of dose or image quality, early termination of the evaluation may be necessary. The decision to terminate the evaluation would be taken by the national office in consultation with the clinical director and medical physics staff involved in the evaluation.

This publication was archived on 05 August 2016

5. TECHNICAL EVALUATION

5.1 Critical examination

Once the equipment is installed, the supplier/installer should arrange for a critical examination in line with the requirements of the *Ionising Radiations Regulations*.[2] This ensures that the safety features and warning devices operate correctly and that people are sufficiently protected from exposure to ionising radiation. The critical examination will frequently be performed by the local mammography physics service.

5.2 Acceptance

The project leader should ensure that the correct equipment, documentation and all the required options and accessories to allow full clinical use have been supplied. The supplier should be asked to demonstrate satisfactory operation of the equipment. Any omissions, problems or discrepancies should be rectified as soon as possible.

5.3 Electrical and mechanical safety checks

These form an important part of the evaluation and should be organised by the evaluation centre through the usual local channels or by arrangement with the local mammography physics service. Advice on checks can be sought from the National Coordinating Centre for the Physics of Mammography (NCCPM) in Guildford.

5.4 Commissioning and performance testing

The evaluation centre must arrange for the local mammography physics service to perform a series of installation, performance and radiation safety checks prior to clinical use of the machine. The physicists carrying out these checks must have appropriate experience and be trained in the testing of mammography x-ray equipment[3] and should be routinely involved in the NHSBSP.

The physics test methods and protocols should broadly follow the procedures described in the latest edition of IPEM Report number 89[4] or the tests agreed for digital equipment.[1,5–7] A physics report should be presented as part of the evaluation process. In addition to a description of the tests performed and the results, reference should be made to specific problems encountered during installation and commissioning, such as equipment shortcomings, and modifications made by the supplier/manufacturer.

5.5 Technical evaluation by the CEP

A full technical evaluation of the machine will be performed by the CEP subject to the submission of a formal proposal through the CEP project selection and prioritisation process and agreement by the CEP Prioritisation Board. Evaluations with analogue systems will be conducted with reference to Medical Devices Agency (MDA) guidance notes.[8] Evaluations of digital systems will be conducted with reference to NHSBSP guidance on testing digital mammography systems.[5] The CEP evaluation will highlight areas such as novel design features and modes of operation, and new methods of image acquisition. These measurements should normally be completed in 2–3 days. For certain installations, members of the medical physics group at CEP or NCCPM may attend or perform the electrical and mechanical safety checks and attend or assist with the commissioning and performance testing. The equipment must not progress to a full clinical evaluation until the technical evaluation has demonstrated that it meets the required NHSBSP standards.

This publication was archived on 05 August 2016

6. CLINICAL EVALUATION

6.1 Staffing

The clinical evaluation should be coordinated by an experienced mammography radiographer, who may also be the project leader. The radiographic staff must be prepared for the extra work involved in using a new machine and the associated record keeping and data collation. Arrangements should be made with the supplier for applications training before the start of the clinical evaluation

6.2 Record keeping

Radiographers working on the machine under evaluation are required to keep details of all images taken. Records should be stored in such a way that they can be retrieved and reviewed at any point in time.

Standard recording forms are provided in this document for both film-screen and digital equipment (Appendices 3 and 4 respectively). The forms may, by agreement, be modified for specific equipment or situations. The forms are available on the NHS Cancer Screening Programmes website (www.cancerscreening.nhs.uk) in Microsoft Word and/or Excel formats as well as in this publication.

A note should be made of all service visits to allow evaluation of the reliability of the machine and the level of service provided by the supplier and/or manufacturer. NHSBSP equipment fault report forms (form 4) should be completed as for existing equipment. The original should be forwarded to the NCCPM. A copy should be kept with the evaluation records.

Evaluation centres should be familiar with the MDA guidance document[8] and with equipment evaluation reports on similar equipment. Recent reports can be found on the PASA and NHS Cancer Screening Programmes websites (www.pasa.nhs.uk/PASAweb/NHSprocurement/CentreforevidencebasedPurchasing/LandingPAge.htm and www.cancerscreening.nhs.uk).

6.3 Report of the evaluation

The evaluation data must be collated and an evaluation and clinical assessment report summarising the findings of the radiographers, the radiologists and local physicists must be prepared for publication. The report should comment on operation and specific features of the machine and refer to the level of service provided by the supplier, the competence of service staff and the availability of clinical applications training and support. If necessary, the report may include photographs and illustrations. Guidance on writing the report is included in Appendix 5.

This publication was archived on 05 August 2016

7. ROUTINE QUALITY CONTROL MEASUREMENTS

7.1 Film-screen systems

The routine quality assurance control should comply with the requirements of *Quality Assurance Guidelines for Mammography Including Radiographic Quality Control*.[9] It is essential that film processing is maintained within acceptable limits.

The collection of exposure data (form 1) is necessary to allow a dose survey to be completed using standard software developed for the NHSBSP. Details of this can be found on the NCCPM website (www.nccpm.org).

Extra measurements to supplement the routine measurements could include monitoring of tube output and tube voltage and the evaluation of image quality using standard image phantoms. A record of all quality assurance and consistency measurements over the test period should be kept. The local mammography physics service may be asked to assist in the analysis of these data.

7.2 Digital mammography systems

The routine quality control tests should comply with *Routine Quality Control Tests for Full Field Digital Mammography Systems*.[11] Paired comparative imaging, where possible, of biopsy, excision and mastectomy specimens should be undertaken on both analogue and digital systems. When the digital images have been judged by the radiologist in charge to be at least as good as the analogue images, the digital system may be used for assessment cases and symptomatic cases, subject to all necessary local approvals being granted. The system may be used for screening only when it has been demonstrated that satisfactory results are being achieved for assessment and symptomatic examinations.

This publication was archived on 05 August 2016

8. REPORT PREPARATION AND PUBLICATION

The project leader at the breast screening centre performing the evaluation will prepare the evaluation and clinical assessment report. A report template and guidance on writing the report are given in Appendix 5. The clinical report should be submitted in draft for review by the national office within three months of completion of the clinical evaluation.

The outcomes of the evaluation will be discussed by a group of NHSBSP representatives consisting of the evaluation site, the NCCPM and a radiographer and a radiologist with relevant experience. This group will determine the suitability of the equipment for use in breast screening by reviewing the available information.

The final draft of the report will be sent to the supplier for comment before publication by the NHS Cancer Screening Programmes as an NHSBSP Equipment Report.

This publication was archived on 05 August 2016

REFERENCES

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2. *The Ionising Radiations Regulations 1999* (SI 1999 No 3232). The Stationery Office, 1999.
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4. *The Commissioning and Routine Testing of Mammographic X-ray Systems*. Institute of Physics and Engineering in Medicine, 2005 (IPEM Report 89).
5. *Commissioning and Routine Testing of Full Field Digital Mammography Systems*. NHS Cancer Screening Programmes, 2006 (NHSBSP Equipment Report 0604, version 2, available at www.cancerscreening.nhs.uk).
6. *Recommended Standards for the Routine Performance Testing of Diagnostic X-ray Imaging Systems*. Institute of Physics and Engineering in Medicine, 2005 (IPEM Report 91).
7. *Assessment of Display Performance for Medical Imaging Systems*. American Association of Physicists in Medicine, 2005 (AAPM On-line Report No 03, available at www.aapm.org/pubs/reports/OR_03.pdf).
8. *Further Revisions to Guidance Notes for Health Authorities and NHS Trusts on Mammographic X-ray Equipment for Breast Screening*. Medical Devices Agency, 2001 (Evaluation Report 01011).
9. *Quality Assurance Guidelines for Mammography Including Radiographic Quality Control*. NHS Cancer Screening Programmes, 2006 (NHSBSP Publication No 63).
10. *Breast Dose Surveys in the NHSBSP: Software and Instruction Manual*, version 2. NHS Cancer Screening Programmes, 2004 (NHSBSP Equipment Report 0405, available at www.cancerscreening.nhs.uk).
11. *Routine Quality Control Tests for Full Field Digital Mammography Systems*. NHS Cancer Screening Programmes, 2007 (NHSBSP Equipment Report 0702).

OTHER USEFUL EQUIPMENT PUBLICATIONS

12. *Review of NHSBSP Equipment and Equipment Faults.* Produced six-monthly by the NHS Cancer Screening Programmes (internal report).
13. *Medical Electrical Installation Guidance Notes (MEIGaN)*. Medicines and Healthcare products Regulatory Agency (MHRA), 2005.
14. *Technical Requirements for the Supply and Installation of Equipment for Diagnostic Imaging and Radiotherapy.* Department of Health, 1989 (Document TRS 89).
15. *Guidance Notes for Health Authorities and NHS Trusts on Requirements for Breast Screening Mobile Trailers and Drawing Vehicles.* Medical Devices Directorate, 1994 (Evaluation Report MDD/93/33).
16. *Guidance Notes for NHS Trusts on Requirements for Mobile Trailers for Breast Screening.* Medicines and Healthcare products Regulatory Agency (MHRA), 2003 (MHRA Evaluation Report 03043).

This publication was archived on 05 August 2016

APPENDIX 1: SERVICE LEVEL AGREEMENT FOR FILM-SCREEN SYSTEMS

The service level agreement should be completed before the evaluation starts. This outlines what is required from the centre in terms of the evaluation. Specific project objectives may also need to be agreed with the centre and the NHSBSP national office.

Information about the equipment evaluated and the evaluation centre should be documented.

This publication was archived on 05 August 2016

SERVICE AGREEMENT FOR THE EVALUATION OF ANALOGUE EQUIPMENT FOR THE NHS BREAST SCREENING PROGRAMME

Between the NHSBSP and _____ Breast Screening Centre

Date _____

Equipment to be evaluated _____

1. Description

This agreement covers the evaluation of equipment for use in the NHS Breast Screening Programme (NHSBSP) in accordance with the *Guidance Notes for Equipment Evaluation* (NHSBSP Equipment Report 0703), a copy of which has been provided to the breast screening centre undertaking the work.

2. Fees

The NHSBSP will reimburse the expenses incurred for the additional work undertaken by staff in the evaluation of a unit of mammography x-ray equipment up to the maximum amount stated below. The agreed payment will be made on production of a report of the evaluation and clinical assessment.

2.1 For the preparation of a report based on an **evaluation protocol** and **data sheets** provided by the NHSBSP on equipment installed by arrangement with the NHSBSP in a breast screening centre that meets the eligibility criteria set out in the *Guidance Notes on Equipment Evaluation*; the purpose of the report is to provide technical and clinical information to enable prospective purchasers in the NHS to determine the suitability of the equipment for their intended application.

Negotiable up to £5000

2.2 For the preparation of a report based on an **evaluation protocol** and **data sheets** provided by the NHSBSP on equipment installed and used by a breast screening centre which meets the eligibility criteria set out in the *Guidance Notes on Equipment Evaluation*; the purpose of the report is to benefit the breast screening centre or the equipment supplier.

Negotiable up to £2000

2.3 For other equipment such as accessories and other ancillary equipment, lesser amounts will be agreed with the breast screening centre before the commencement of this agreement.

The centre undertaking the evaluation will be responsible for dissemination of the fees to the various internal groups and outside agencies involved in commissioning, safety and physics checks, clinical use, collation of data and reporting writing.

Evaluation category (please circle) 2.1 2.2 2.3

Fee £ _____

This publication was archived on 05 August 2016

3. Personnel

	Name	Contact telephone number
Superintendent radiographer		
Lead radiologist		
Breast screening centre project leader		
Breast screening centre physicist		
NHSBSP project supervisor		
KCARE project manager		

4. Timescale

Projected date of installation	
Projected duration of evaluation	
Projected date of completed report	

5. Additional information

Signed:

NHSBSP representative _____

Breast screening centre _____

This publication was archived on 05 August 2016

EQUIPMENT EVALUATED AND EVALUATION CENTRE INFORMATION

1. Details of equipment evaluated and evaluation centre

1.1	Equipment model	
1.2	Manufacturer	
1.3	Supplier	
1.4	Serial number(s)	
1.5	Evaluation centre	
1.6	Breast screening centre project leader and telephone number	

2. Installation

2.1	Date of start of installation	
2.2	All adjustments made to suit local radiographic requirements by the installation engineer should be recorded. The engineer should confirm that all adjustments made conform with the manufacturer's installation protocol	
2.2.1	Adjustments to suit local radiographic requirements	
2.2.2	Comment by engineer on adjustments made	
2.3	Date of acceptance for clinical use	
2.4	Date of start of clinical evaluation	
2.5	Date of completion of clinical evaluation	

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3. Film and film handling equipment

(Note: It is important that these are not changed during the evaluation period.)

3.1	Manufacturer and type of film used during the evaluation	
3.2	Manufacturer and model of film processor	
3.3	Processing time dry to dry	
3.4	Developer temperature	
3.5	Manufacturer and type of processing chemicals	
3.6	Make and type of cassettes and screens used during the evaluation	
3.7	Total number of clinical films taken during the evaluation period	
3.8	Total number of sensitometry films taken during the evaluation period	

4. Number of examinations undertaken

4.1	Number of women screened	
4.2	Number of women assessed	
4.3	Number of women examined with magnification	
4.4	Number of stereotactic examinations	

This publication was archived on 05 August 2016

This publication was archived on 05 August 2016

APPENDIX 2: SERVICE LEVEL AGREEMENT FOR DIGITAL SYSTEMS

The service level agreement should be completed before the evaluation starts. This outlines what is required from the centre in terms of the evaluation. Specific project objectives may also need to be agreed with the centre and the NHSBSP national office.

Information about the equipment evaluated and the evaluation centre should be documented.

This publication was archived on 05 August 2016

SERVICE AGREEMENT FOR THE EVALUATION OF DIGITAL IMAGING EQUIPMENT FOR THE NHS BREAST SCREENING PROGRAMME

Between the NHSBSP and _____ Breast Screening Centre

Date _____

Equipment to be evaluated _____

1. Description

This agreement covers the evaluation of equipment for use in the NHS Breast Screening Programme (NHSBSP) in accordance with the *Guidance Notes for Equipment Evaluation* (NHSBSP Equipment Report 0703), a copy of which has been provided to the breast screening centre undertaking the work.

2. Fees

The NHSBSP will reimburse the expenses incurred for the additional work undertaken by staff in the evaluation of a unit of mammography x-ray equipment up to the maximum amount stated below. The agreed payment will be made on production of a report of the evaluation and clinical assessment.

2.1 For the preparation of a report based on an **evaluation protocol** and **data sheets** provided by the NHSBSP on equipment installed by arrangement with the NHSBSP in a breast screening centre that meets the eligibility criteria set out in the *Guidance Notes on Equipment Evaluation*, for the specific purpose of providing technical and clinical information that will enable prospective purchasers in the NHS to determine its suitability for their intended application.

Negotiable up to £5000

2.2 For the preparation of a report based on an **evaluation protocol** and **data sheets** provided by the NHSBSP on equipment installed and used by a centre which meets the eligibility criteria set out in the *Guidance Notes for Equipment Evaluation*, for the benefit of the centre or the equipment supplier.

Negotiable up to £2000

2.3 For other equipment such as accessories and other ancillary equipment, lesser amounts will be as agreed with the centre before the start of this agreement.

The centre undertaking the evaluation will be responsible for dissemination of the fees to the various internal groups and outside agencies involved in commissioning, safety and physics checks, clinical use, collation of data and reporting writing.

Evaluation category (please circle) 2.1 2.2 2.3

Fee £ _____

This publication was archived on 05 August 2016

3. Personnel

	Name	Contact telephone number
Superintendent radiographer		
Lead radiologist		
Breast screening centre project leader		
Breast screening centre physicist		
NHSBSP project supervisor		
KCARE project leader		
KCARE project manager		

4. Timescale

Projected date of installation	
Projected duration of evaluation	
Projected date of completed report	

5. Additional information

Signed:

NHSBSP representative _____

Breast screening centre _____

This publication was archived on 05 August 2016

EQUIPMENT ASSESSED AND EVALUATION CENTRE INFORMATION

1. Details of equipment assessed and centre

1.1	Equipment model	
1.2	Manufacturer	
1.3	Supplier	
1.4	Serial number(s)	
1.5	Evaluation centre	
1.6	Breast screening centre project leader and telephone number	

2. Installation

2.1	Date of start of installation	
2.2	All adjustments made to suit local radiographic requirements by the installation engineer should be recorded. The engineer should confirm that all adjustments made conform with the manufacturer's installation protocol	
2.2.1	Adjustments to suit local radiographic requirements	
2.2.2	Comment by engineer on adjustments made	
2.3	Date of acceptance for clinical use	
2.4	Date of start of clinical evaluation	
2.5	Date of completion of clinical evaluation	

This publication was archived on 05 August 2016

3. Details of reporting workstation and hardcopy device

(Note: It is important that these are not changed during the evaluation period.)

3.1	Manufacturer and type of reporting workstation	
3.2	Number, manufacturer, type and resolution (pixel matrix) of monitors	
3.3	Software type and version	
3.4	Manufacturer and type of hardcopy device	
3.5	Resolution (pixel matrix) of hardcopy device	

4. Number of examinations undertaken

4.1	Number of excision specimens	
4.2	Number of mastectomy specimens	
4.3	Number of symptomatic patients	
4.4	Number of core biopsy specimens	
4.5	Number of women screened	
4.6	Number of women assessed	
4.7	Number of women examined with magnification – physical and optical	
4.8	Number of stereotactic examinations	

This publication was archived on 05 August 2016

This publication was archived on 05 August 2016

APPENDIX 3: ANALOGUE EQUIPMENT EVALUATION FORMS

Examples of the layouts and the headings are given in this appendix.

Forms 1 to 9 are used at different stages during the evaluation, as appropriate. Evaluation centres should set up their own spreadsheets for Forms 1–3, 5, 7 and 9.

Forms 1, 2 and 3 are used routinely during the evaluation to record exposure and image quality data, depending on the mode of operation of the equipment.

Form 4 is the NHSBSP equipment fault reporting form (available at www.nccpm.org). It should be used each time an equipment fault occurs. The original should be forwarded to the National Coordinating Centre for the Physics of Mammography (NCCPM). A copy should be kept with the evaluation data.

Form 5 records details of the mammography sessions during the evaluation. It is particularly important to record this information for screening sessions to allow the average examination time per woman to be calculated.

Form 6 records mammography practitioners' observations and findings. It should be completed soon after the start of the assessment and again towards the end of the evaluation period. All aspects of the equipment and its operation should be covered, including magnification and stereotactic operation, if provided.

Form 7, the mammography quality assurance record, is used to collect data from the routine automatic exposure control (AEC) tests.

Form 8 is the film reader's report. A copy of this form should be completed by at least two film readers, and preferably by each film reader reporting on images from the unit.

Form 9 records the assessment of image quality. The film reader records data on the clinical image quality for a sample of the images from the system under evaluation.

This publication was archived on 05 August 2016

NHSBSP ANALOGUE EQUIPMENT EVALUATION (FORM 1)

Exposure and image quality record: screening and assessment mammograms

Unit _____ Evaluating centre _____

Exposure factors												Mammography practitioner's comments
1	2	3	4	5	6	7	8	9	10	11	12	13
Date	Image no.	Patient ID	View	Operation mode	AEC setting	AEC position	Target/ filter	kV	mAs	Compression thickness	Compression force	Comments on image quality

1. Format as dd/mm/yy.
3. Use patient ID number.
4. Use CC, MLO or LAT.
5. For example, autokV.
6. Use density setting, eg –3 to +3.
7. Use CWE – chest wall edge or M – middle.
11. Thickness in cm.
12. Force in N.
13. For example, gridlines, blurring, artefacts, film density, repeats, repeat reasons.

This publication was archived on 05 August 2016

NHSBSP ANALOGUE EQUIPMENT EVALUATION (FORM 2)

Exposure and image quality record: magnification mammograms

Unit _____ Evaluating centre _____

Exposure factors													Mammography practitioner's comments	Film reader/radiologist's comments		
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Date	Image no.	Patient ID	View	Magnification factor	Operation mode	AEC setting	AEC position	Target/ filter	kV	mAs	Compression thickness	Compression force	Comments on image quality	Clinical image quality	Comments	Initials

1. Format as dd/mm/yy.
3. Use patient ID number.
4. Use CC, MLO or LAT.
6. For example, autokV.
7. Use density setting, eg –3 to +3.
8. Use CWE – chest wall edge or M – middle.
12. Thickness in cm.
13. Force in N.
14. For example, gridlines, blurring, artefacts, film density, repeats, repeat reasons.
15. Use E – excellent, G – good, S – satisfactory, P – poor, I – inadequate.

This publication was archived on 05 August 2016

NHSBSP ANALOGUE EQUIPMENT EVALUATION (FORM 3)

Exposure and image quality record: stereo examinations

Unit _____ Evaluating centre _____

Exposure factors											Mamography practitioner/radiologist/clinician's comments		
1	2	3	4	5	6	7	8	9	10	11	12	13	14
Date	Image no.	Patient ID	View	Side	Operation mode	AEC setting	Target/ filter	kV	mAs	Calibration checked?	Clinical image quality	Comments on particular biopsy devices used	Initials

1. Format as dd/mm/yy.
3. Use patient ID number.
4. Use CC, MLO or LAT.
5. Use S – scout, L – left, R – right.
6. For example, autokV.
7. Use density setting, eg –3 to +3.
11. Use Y – yes, N –no.
12. Use E – excellent, G – good, S – satisfactory, P – poor, I – inadequate.
13. For example, lateral arm, mammotome.

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NHSBSP ANALOGUE EQUIPMENT EVALUATION (FORM 5)

Record of mammography sessions

Unit _____

Evaluating centre _____ Mobile or static _____

Mammography sessions					Mammography practitioner's comments	
1	2	3	4	5	6	
Date	Duration of session	Number of women invited	Number of women screened	Number of repeats/ recalls	Comments	Initials

1. Format as dd/mm/yy.
2. Hours and minutes.

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NHSBSP ANALOGUE EQUIPMENT EVALUATION (FORM 6)

Mammography practitioner observations and findings

A copy of this form should be completed near the start and again towards the end of the evaluation

Unit _____ Evaluating centre _____

General	Poor	Satisfactory	Good	Excellent	Comments
1. How good was the operator's manual?					
2. How good was the user training provided by supplier?					
3. 3.1 How do you rate the unit's ease of use? 3.2 How do you rate the unit's help in minimising fatigue?					
4. Were the x-ray exposures times acceptable? (If not, explain, eg hit backup timer frequently)					
5. Setting for radiographic views 5.1 How do you rate the rotation of the support arm? 5.2 Visibility of the set angle?					
6. Setting position of breast support table How do you rate the facility for positioning the height of the breast support table?					
7. Range of movements Adequacy of the range of movements offered by the unit?					
8. Compression How effective was the compression system? Visibility of compression force from breast support table?					
9. AEC detector positioning 9.1 Ease of setting? 9.2 Adequacy of detector position options?					
10. Visibility of AEC detector marking					
11. Ease of insertion and removal of cassettes					
12. Performance of supplied radiographic view markers					
13. Effectiveness of brakes How well did the brakes work? (eg was there any backlash or movement?)					
14. Comfort of women 14.1 Did the women experience excessive discomfort or pain? 14.2 Were there any sharp corners, etc					
15. Range of controls and indicators 15.1 Were all the expected controls present? 15.2 Were they easy to find and use? 15.3 How could they be improved?					

This publication was archived on 05 August 2016

16. How do you rate the choice of collimators supplied for spot compression?					
17. Confidence of good results What was your level of confidence in the machine?					
18. Hazards Were there any potentially hazardous areas accessible to either you or the woman? (eg hot spots)					
19. Equipment cleaning Ease of cleaning the machine?					
Were there instructions in the manual?					Yes/No
20. Patient and exposure data and post exposure print out facility (if available)					
21. Did the x-ray set performance limit patient throughput? (If so, say why, eg to allow for cooling)					Yes/No
22. Overall film quality How would you rate the image quality of films taken on this unit?					
23. Relative image quality Was the image quality attained by this unit better, worse or the same as that by other analogue units?					Worse/same/better
24. Any additional comments on general performance					

Magnification	**Poor**	**Satisfactory**	**Good**	**Excellent**	**Comments**
1. Rate the ease with which the magnification equipment may be assembled and dismantled					
2. Rate the ease of use of the magnification breast support table					
3. Grade how the magnification support table performs					
4. Visibility of indication of focal spot size selected?					
5. Removal and insertion of collimator plates Range of collimators Operation of automatic diaphragms					
Stereo	**Poor**	**Satisfactory**	**Good**	**Excellent**	**Comments**
1. Rate the ease with which stereotactic equipment may be assembled and dismantled					
2. How easy is the stereo to clean?					
3. Ease of rotation of support arm with stereo assembly fitted?					
4. Overall, how easy to use was the stereo assembly?					
5. Comment on the accuracy of the stereo in needle positioning					

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NHSBSP ANALOGUE EQUIPMENT EVALUATION (FORM 7)

Mammography quality assurance record: AEC performance

Unit _____ Evaluating centre _____

AEC performance																Mammography practitioner's comments	
1	2	3	4			5			6				7				8	9
Date	Operation mode	AEC setting	2 cm Perspex			4 cm Perspex			6 cm Perspex (indicate target/filter if not Mo/Mo)				7 cm Perspex (indicate target/filter if not Mo/Mo)				Comments	Initials
			kV	OD	mAs	kV	OD	mAs	kV	Target/ filter	OD	mAs	kV	Target/ filter	OD	mAs		

1. Format as dd/mm/yy.
2. For example, autokV.
3. Use density setting, eg –3 to +3.

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NHSBSP ANALOGUE EQUIPMENT EVALUATION (FORM 8)

Radiologist's or film reader's report

Unit _____

Evaluating centre _____

At least two, and preferably all, radiologists or other film readers reporting films produced on this unit are asked to provide subjective opinions on image quality and to rate the unit's performance against other mammographic units of their experience. To judge whether opinions on performance have changed over the period of the assessment period, a copy of this form should be completed near the start and again towards the end of the evaluation.

Date _____

Name or code of radiologist _____

Type and make of viewer used _____

Summary data on subjective opinion of diagnostic quality of films viewed (enter approximate number of films in boxes)

	Excellent	Good	Satisfactory	Poor	Inadequate
Full size					
Magnified					
Stereo					

Reasons for films of inadequate image quality (enter approximate number of films in boxes)

	Exposure factors	Positioning	Movement blur	Other
Full size				
Magnified				
Stereo				

If other, state reason

Form 9 may be used to grade different aspects of film quality for a sample of films for the system under evaluation.

This publication was archived on 05 August 2016

NHSBSP ANALOGUE EQUIPMENT EVALUATION (FORM 9)

Assessment of image quality of clinical films by radiologist or film reader

This form may be used to grade different aspects of image quality for a sample of images for the system under evaluation.

1	2	3	4	5	6	7	8
Date	**Image no.**	**Exposure**	**Contrast**	**Sharpness**	**Breast composition**	**Overall**	**Initials**

1. Format as dd/mm/yy.
3. Use E – excellent, G – good, S – satisfactory, P –poor, I –inadequate.
4. Use E – excellent, G – good, S – satisfactory, P –poor, I –inadequate.
5. Use 1 – blurred, 2 – satisfactory, 3 – sharp.
6. Use F – fatty, M – mixed, D – dense.
7. Use E – excellent, G – good, S – satisfactory, P –poor, I –inadequate.

This publication was archived on 05 August 2016

APPENDIX 4: DIGITAL EQUIPMENT EVALUATION FORMS

Examples of the layouts and the headings are given in this appendix.

Forms 1–10 should be used at appropriate stages of the evaluation. Evaluation centres should set up their own spreadsheets for Forms 1–3, 5, 8 and 10.

Form 1 records information that can form the basis of the patient dose audit. Check the NCCPM data collection tool (www.nccpm.org) to ensure that all required data are collected.

Form 2 records magnification mammograms. Omit if the equipment does not have a physical magnification capability, but include if it has an extra-high resolution mode. The evaluation report should include information on the use of optical zoom at the workstation.

Form 3 records exposure and image quality for stereo examinations.

Form 4 is the NHSBSP equipment fault reporting form (available at www.nccpm.org). It should be used each time an equipment fault occurs. The original should be forwarded to the National Coordinating Centre for the Physics of Mammography (NCCPM). A copy should be kept with the evaluation data.

Form 5 gives one method of collecting data to enable evaluation of individual examination times. Alternative methods may be used as long as they yield this information. The evaluation should establish whether the equipment will enable standard appointment times to be maintained or reduced.

Form 6 should be completed by all mammography practitioners using the equipment.

Forms 7a to 7f are the radiographic quality control forms. These are in Microsoft Excel format and are downloadable from NHS Cancer Screening Programmes website (www.cancerscreening.nhs.uk). The spreadsheets have a number of formulae in place to help with calculations as appropriate. Further formats and information on the tests themselves can be found in *Routine Quality Control Tests for Full Field Digital Mammography Systems*.[11]

Form 8 is a method of collecting information on direct comparison between film-screen and digital images. Alternative methods may be acceptable as long as comparable information is obtained and included in the evaluation report.

Form 9 should be completed by each film reader and radiologist using the workstation.

Form 10 is for recording the specimen radiography that is carried out in the initial stages of the evaluation and which forms the basis for the comparisons recorded on Form 8.

This publication was archived on 05 August 2016

NHSBSP DIGITAL EQUIPMENT EVALUATION (FORM 1)

Exposure and image quality record: screening and assessment images – full field examinations

Unit _____ Evaluating centre _____

Exposure factors											Mammography practitioner's comments
1	2	3	4	5	6	7	8	9	10	11	12
Date	Accession no.	View	Field size	Operation mode	Dose	Target/ filter	kV	mAs	Compression thickness	Compression force	Comments on image quality

1. Format as dd/mm/yy.
2. Use unique identifier.
3. Use CC, MLO or LAT.
5. For example, autokV.
6. Dose indication or dose.
10. Thickness in cm.
11. Force in N.
13. For example, gridlines, blurring, artefacts, film density, repeats, repeat reasons.

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NHSBSP DIGITAL EQUIPMENT EVALUATION (FORM 2)

Exposure and image quality record: magnification images

Unit _____ Evaluating centre _____

Exposure factors													Mammography practitioner's comments	Film reader/radiologist's comments		
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Date	Accession no.	View	Type of magnification	Magnification factor	Field size	Operation mode	Dose	Target/ filter	kV	mAs	Compression thickness	Compression force	Comments on image quality	Clinical image quality	Comments	Initials

1. Format as dd/mm/yy.
2. Use unique identifier.
3. Use CC, MLO or LAT.
4. Use P – physical magnification or H – high resolution mode.
7. For example, AEC, autokV.
8. Dose indicator or dose.
12. Thickness in cm.
13. Force in N.
14. For example, gridlines, blurring, artefacts, film density, repeats, repeat reasons.
15. Use E – excellent, G – good, S – satisfactory, P – poor, I – inadequate.

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NHSBSP DIGITAL EQUIPMENT EVALUATION (FORM 3)

Exposure and image quality record: stereo examinations (use one line for each exposure)

Unit _____ Evaluating centre _____

Exposure factors										Mamography practitioner/radiologist/clinician's comments		
1	2	3	4	5	6	7	8	9	10	11	12	13
Date	Accession no.	View	Side	Operation mode	Dose	Target/ filter	kV	mAs	Calibration checked?	Clinical image quality	Comments on particular biopsy devices used	Initials

1. Format as dd/mm/yy.
2. Use unique identifier.
3. Use CC, MLO or LAT.
4. Use S – scout, L – left, R – right.
5. For example, AEC, autokV.
6. Dose indication or dose.
10. Use Y – yes, N –no.
11. Use E – excellent, G – good, S – satisfactory, P – poor, I – inadequate.
12. For example, lateral arm, mammotome.

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NHSBSP DIGITAL EQUIPMENT EVALUATION (FORM 5)

Record of individual examination times

Unit _____ Evaluating centre _____

Date _____ Name of person recording times _____
(an independent person should monitor times with a stopwatch)

Was the clinic list loaded onto the system? Yes / No

Was the mammography practitioner working alone? Yes / No If no, what assistance was provided? _____

Did the women change in the room or in a cubicle? _____

Mammography sessions			Mammography practitioner's comments
1	2	3	4
Time taken	Screen	Bucky size changed?	Comments

1. Time taken from woman entering mammography room to woman leaving mammography room in minutes and seconds.
2. Use F – first, S – subsequent.
3. Use Y –yes, N – no.
4. For example, disability, discussion of clinical signs, other factors affecting time taken.

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NHSBSP DIGITAL EQUIPMENT EVALUATION (FORM 6)

Mammography practitioner observations and findings

A copy of this form should be completed by each mammography practitioner when comfortable with use and operation of the equipment.

Unit _____ Evaluating centre _____

General	Poor	Satisfactory	Good	Excellent	Comments
1. How good was the operator's manual?					
2. How good was the user training provided by supplier?					
3. 3.1 How do you rate the unit's ease of use? 3.2 How do you rate the unit's help in minimising fatigue?					
4. Were the x-ray exposure times acceptable? (If not, explain, eg hit backup timer frequently)					
5. Setting for radiographic views 5.1 How do you rate the rotation of the support arm? 5.2 Visibility of the set angle?					
6. Setting position of breast support table How do you rate the facility for positioning the height of the breast support table?					
7. Range of movements Adequacy of the range of movements offered by the unit?					
8. Effectiveness of brakes/locks How well did the brakes work? (eg was there any backlash or movement?)					
9. Compression 9.1 How effective was the compression system? 9.2 Visibility of compression force from breast support table?					
10. Comfort of women Tick relevant boxes and/or enter any informative comments made by women					
11. Range of controls and indicators 11.1 Were all the expected controls present? 11.2 Were they easy to find and use?					
12. How do you rate the choice of collimators supplied for spot compression?					
13. How do you rate the time for an image to appear at the acquisition workstation?					
14. How do you rate the image handling and processing facilities at the acquisition workstation?					
15. Overall image quality at the acquisition workstation How would you rate the image quality on this unit?					

This publication was archived on 05 August 2016

16. How easy was it to transfer images to the reporting workstation and to the hardcopy printer (if provided)?					
17. Confidence of good results What was your level of confidence in the machine?					
18. Hazards Were there any potentially hazardous areas accessible to either you or the woman? (eg hot spots)					
19. Equipment cleaning 19.1 Ease of cleaning the machine?					
19.2 Were there instructions in the manual?					Yes/No
20. Patient and exposure data and post exposure print out facility (if available)					
21. Did the digital x-ray system performance limit patient throughput? (If so, say why)					Yes/No
22. Any additional comments on general or imaging performance					

Magnification	**Poor**	**Satisfactory**	**Good**	**Excellent**	**Comments**
1. Rate the ease with which the magnification equipment may be attached and removed					
2. Rate the ease of use of the magnification breast support table					
3. Removal and insertion of collimator plates 3.1 Range of collimators 3.2 Operation of automatic diaphragms					
Stereo	**Poor**	**Satisfactory**	**Good**	**Excellent**	**Comments**
1. Rate the ease with which stereotactic equipment may be attached and removed					
2. How easy is it to clean the stereotactic equipment?					
3. Ease of rotation of support arm with stereo assembly fitted and ease of angulation of x-ray tube assembly?					
4. Overall, how easy to use is the stereo assembly?					
5. Comment on the accuracy of the stereo in needle positioning					
6. Overall image quality How would you rate the image quality of stereo images on this unit?					

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NHSBSP DIGITAL EQUIPMENT EVALUATION (FORM 8)

Assessment of film versus digital image quality

1	2	3	4	5	6	7	8	9	10	11	12	13
Image no.	**Patient ID**		**View**	**Breast composition**	**Overall exposure**	**Overall contrast**	**Sharpness**	**Noise**	**Absolute diagnostic value**	**Relative diagnostic value (normal)**	**Relative diagnostic value (zoom)**	**Comments by radiologist/film reader**
		Film										
		Digital										
		Film										
		Digital										

1. Use image number (analogue) or accession number (digital).
2. Use patient ID number.
4. Use CC, MLO or LAT.
5. Use F – fatty, M – mixed, D – dense.
6. Use 3 – very high, 2 – high, 1 – slightly high, 0 – OK, –1 – slightly low, –2 – low, –3 – very low.
7. Use 3 – very high, 2 – high, 1 – slightly high, 0 – OK, –1 – slightly low, –2 – low, –3 – very low.
8. Use 1 – blurred, 2 – satisfactory, 3 – sharp.
9. Use 1– very noisy, 2 – noisy, 3 – not noisy.
10. Use E – excellent, G – good, S – satisfactory, P – poor, I – inadequate.
11. Use –2 – digital worse than film, –1 – digital slightly worse than film, 0 – digital same as film, +1 – digital slightly better than film, +2 – digital better than film.
12. Use –2 – digital worse than film, –1 – digital slightly worse than film, 0 – digital same as film, +1 – digital slightly better than film, +2 – digital better than film.

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NHSBSP DIGITAL EQUIPMENT EVALUATION (FORM 9)

Reporting workstation: users' observations and findings

A copy of this form should be completed by each user when comfortable with use and operation of the equipment.

Unit _____ Evaluating centre _____

	Poor	Satisfactory	Good	Excellent	Comments (include all specific difficulties)
1. How good was the operator's manual? (state if N/A)					
2. How good was the training provided by the supplier?					
3. How easy is it to adjust the height and angle of the reporting monitors to suit the user?					
4. How easy is it to adjust the height and angle of the database monitor to suit the user?					
5. How do you rate the ease of use of the workstation controls? (complete any applicable) a. Mouse b. Keyboard c. Keypad					
6. How to you rate the image handling tools (zoom, etc)?					
7. Rate visibility and usability of on-screen icons separately					
8. How do you rate the post processing image manipulation (window and level)?					
9. How do your rate the reading/ reporting flow pattern?					
10. If there was a choice of hanging protocols, how easy was it to set these?					
11. Within a hanging protocol, how easy was it to display a different choice of image, ie images performed beyond the standard four?					

This publication was archived on 05 August 2016

	Poor	Satisfactory	Good	Excellent	Comments (include all specific difficulties)
12. How do you rate the time taken between an image being selected and appearing on the screen?					
a. New patient selection b. In-examination change					
13. Did the database or PACS software allow for recording findings under NHSBSP reading protocols?					Yes / No
14. How easy was it to record findings? List any specific difficulties in the comments section					
15. How much of a problem was light from the database screen raising ambient lighting around the reporting monitors?					
16. Did you identify any hazards associated with the workstation or its use?					Yes / No
17. Describe any additional or unusual features or quirks of the system					
18. What is your overall level of satisfaction with the reporting workstation?					

This publication was archived on 05 August 2016

NHSBSP DIGITAL EQUIPMENT EVALUATION (FORM 10)

Exposure and image quality record: specimen radiography

Unit _____ Evaluating centre _____

Exposure factors											Mammography practitioner's comments
1	2	3	4	5	6	7	8	9	10	11	12
Date	Accession no.	Type	Field size	Operation mode	Dose	Target/ filter	kV	mAs	Compression thickness	Compression force	Comments on quality at the acquisition table

1. Format as dd/mm/yy.
2. Use unique identifier.
3. For example, excision biopsy, core biopsy.
5. For example, autokV.
6. Dose indication or dose.
10. Thickness in cm.
11. Force in N.
12. For example, gridlines, blurring, artefacts, film density, repeats, repeat reasons.

This publication was archived on 05 August 2016

This publication was archived on 05 August 2016

APPENDIX 5: GUIDANCE ON DRAFTING EVALUATION REPORTS

This publication was archived on 05 August 2016

General

Abbreviations Please define these the first time they appear in the text.

Appendices These should be used for details which do not sit comfortably in the text (eg technical data, results), but they must be referred to in the text. Number the appendices in the order in which they are cited in the text.

Consistency Please check carefully for consistency (eg in use of terminology or use of abbreviations).

Contents list Not necessary – it is added at typesetting stage, but it may be useful to look at the document in 'Outline view' to help to structure the document.

Equipment manufacturer or supplier Please check correct name for company. Any product information supplied by the company is usually copyright and can be reproduced only with permission. It is generally better not to include this – the company can be cited as the source for further details if necessary. Promotional material for a company or product should not be included.

Figures and tables Please number figures and tables and cite them in order in the text. It is often easier to save them as a separate PDF file. They can then be placed at typesetting stage as close as possible to the relevant text.

Formatting It is not necessary to format the document as this is done as part of the typesetting process. Just use a simple layout and font that you are comfortable working with.

Glossary This may be useful in a lengthy document if there are a lot of unfamiliar abbreviations or technical terms.

Headings Main headings should be in bold capitals and numbered 1, 2, 3 etc. Subsections should be in bold sentence case and numbered 1.1, 1.2, 1.3 etc. Any further subdivisions should be in italic sentence case and numbered 1.1.1, 1.1.2 and so on.

Names of individuals Please check correct spelling (and correct contact details if these are given). Generally, individuals should be named only in the acknowledgements or as the point of contact for further information (in this case, please check that addresses, telephone numbers and email addresses are accurate).

NHSBSP committees or working groups Please check correct titles and use these consistently.

References Include a reference list. Please check carefully that references are cited in the text. Also check that the reference list is accurate and that all references are complete.

Summaries Please check that any summaries (eg executive summaries or conclusions) are consistent with the main text of the report.

Report content

This relates mainly to evaluation reports for digital systems, but a similar content should be followed for reports on analogue systems.

Executive summary This should be completed when the report conclusions have been finalised and should cover the main outcomes of the evaluation.

This publication was archived on 05 August 2016

This publication was archived on 05 August 2016

Introduction Describe here the objectives of the evaluation. List who did which parts of the work. Include the physics testing, radiography, assessment of cost effectiveness etc.

Objectives of the evaluation Set out the main objectives of the evaluation here.

System description Describe the equipment in more detail. Include layout diagrams and pictures in an appendix if necessary.

Acceptance testing, commissioning and performance testing A short description of the testing procedures and outcomes. Include what was done and why. The main results should be provided in an appendix. An analysis of actual doses should be included.

Routine quality control Describe what was undertaken and include an analysis of the results.

Assessment of image quality Include the comparative work and test object work.

Data on screening conducted Provide number of women screened, times etc; describe how the clinics worked. For digital systems, compare with a similar film-screen system.

Data on assessments conducted Provide number of women assessed, use of magnification tables, stereo attachment.

Equipment reliability Provide information here on the uptime of the unit based on the number of hours it was actually in use over the total expected. Include copies of fault reports in an appendix.

Electrical and mechanical robustness Include comments about the safety of the unit and any van fixing kit used, how it was moved, any set up issues on sites, any problems with van moves.

Mammography practitioners' comments and observations Include any comments about ease of use and problems encountered. For digital systems, comments on the ergonomics of the acquisition station and gantry can be included here.

Radiologists' comments and observations Include a report from the radiologists/film readers on the practicalities of soft copy screen reading, use of tools, time taken to read the images compared with film, how previous films were handled, viewing conditions. Any conclusions relating to the soft copy workstation can be included here.

Information systems Make comments here on the archiving methods and information system links with the mammography machine/integration with PACS.

Confidentiality Make comments on how patient confidentiality was maintained.

Security issues Make comments here on data security.

Training Comment here about what applications training would be required to become proficient at using both the mammography equipment and the soft copy reading workstation.

Conclusions and recommendations Draw together the conclusions and ensure that the objectives of the eluation have been addressed.

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