NHS
Cancer Screening Programmes

Guidance notes for equipment evaluation and protocol for user evaluation of imaging equipment for mammographic screening and assessment

NHSBSP Equipment Report 1411

September 2014

About the NHS Cancer Screening Programmes

The national office of the NHS Cancer Screening Programmes is operated by Public Health England. Its role is to provide national management, coordination, and quality assurance of the three cancer screening programmes for breast, cervical, and bowel cancer.

About Public Health England

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

www.gov.uk/phe

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Document objective (clinical/healthcare/social questions covered)	This document provides a framework for practical evaluations of new equipment for use in the NHSBSP. These are required, in combination with a technical evaluation, before equipment is used in the NHSBSP.
Population affected	Women screened and assessed within the NHSBSP
Target audience	Evaluation Centres, QA Radiographers, Physicists
Archived	Current Document

Contents

Acknowledgements

This is the fourth revision of these guidance notes. The current document supersedes the previous version, which was published in October 2013. The guidance now only includes protocols for the evaluation of digital equipment. This version contains additional forms for radiographer quality control, and special forms for tomosynthesis evaluations.

The guidance notes have been approved by the NHS Breast Screening Programme (NHSBSP) Equipment Group.

Executive summary

Mammographic X-ray equipment used in the NHS Breast Screening Programme (NHSBSP) is evaluated in centres where staff routinely perform screening and assessment examinations of women. Evaluations are undertaken to assess the use of equipment in a practical, clinical setting and are not intended to be clinical trials.

Currently, a number of breast screening centres in England undertake the practical evaluation of equipment using protocols provided by the NHSBSP. These evaluations are staged processes, starting with a technical evaluation by the National Coordinating Centre for the Physics of Mammography (NCCPM). If the technical evaluation is satisfactory, and if national office and the local physics service agree to progress the equipment to the next stage, a subsequent practical evaluation is conducted. The progress of current evaluations is shown on the NHS Cancer Screening Programmes website:

www.cancerscreening.nhs.uk

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

- determine the suitability of the equipment for use within the NHSBSP
- assist potential purchasers in making their choice of equipment
- provide potential users with performance data about equipment
- provide potential users with a record of the practical experience of using the equipment in the NHSBSP
- enable comparisons to be made with other pieces of equipment (consistent performance standards are used for each type of equipment and comparisons can therefore be made by studying several reports)

1. Selection of equipment for evaluation

Equipment manufacturers normally request an NHSBSP evaluation of new models, or of models that have been significantly altered. These requests should be directed through NCCPM or the national office of the Cancer Screening Programmes (CSP). Standard proformas to be used for these requests are in Appendices 3, 4 and 5. On receipt of such a request, the national office and NCCPM will begin discussions, and will make a decision on the appropriateness of proceeding to a technical evaluation, and subsequently a practical evaluation.

A representative from NCCPM will report on the progress of evaluations at biannual meetings of the NHSBSP National Coordinating Group for Equipment. The NHS CSP will also report on the progress of reports using the NHS CSP website.

Before any new technology is considered for evaluation it should have been approved for use in screening by the Department of Health's Advisory Committee on Breast Cancer Screening. This group considers the body of evidence available and makes recommendations on the use of a piece of technology in screening or assessment. Any new piece of technology considered for use must be at least as good as the existing technology, and ideally better.

2. Selection of evaluation centres

2.1 Eligibility criteria for evaluation centres

Breast screening centres taking part in the practical evaluation of equipment 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:

- it must be possible to X-ray specimens before the evaluation moves on to the next stage of imaging women
- the equipment must be capable of receiving a worklist from the National Breast Screening System (NBSS)
- the breast screening centre selected for the evaluation should have sufficient throughput for the period of the evaluation
- a robust Quality Assurance (QA) system must be in place at the centre, so that it meets all relevant NHSBSP objectives and guidelines[1,2]
- there must be a robust system in place for the images to be stored on PACS. These images must be retrievable when required for comparison with new examinations
- the local mammography physics service, and all radiographers and radiologists involved in the evaluation, must comply with the relevant NHSBSP professional guidelines. Compliance can be confirmed via a recent QA visit report
- mammography screening equipment may require additional evaluation in trailers. This should be carried out only after the equipment (or a similar type of equipment) has been fully evaluated at a static site
- the local physics service should confirm their willingness and ability to support the equipment evaluation at an early stage

Centres may be considered suitable for the evaluation of some systems, but not others.

2.2 Service Level Agreements

A Service Level Agreement (SLA) between the NHSBSP and the evaluation centre is required because a contribution towards the costs of the evaluation is made by the NHSBSP. The template for an SLA is provided in Appendix 1.

The centre undertaking the evaluation is responsible for dissemination of this funding to the various internal groups and outside agencies involved in installing the equipment, conducting safety and performance checks, evaluating its use in a clinical setting, collating data, and writing the final report.

2.3 Project management

A project leader should be appointed by the centre to coordinate the evaluation and make sure that all the required areas are covered while ensuring effective liaison between the screening centre, the supplier/manufacturer/installer and the NHSBSP representatives. Timescales should be established and agreed with the national office representative as soon as the availability of the equipment is confirmed.

Adequate arrangements must be made for delivering applications training to all staff involved in the evaluation. A staged approach should be taken, starting with a technical evaluation completed by NCCPM. The technical evaluation could be carried out offsite, in which case the technical report should be available before the practical evaluation commences. If the technical evaluation is carried out at the practical evaluation site, a delay of at least one month should be planned for, before starting the practical evaluation. NCCPM will produce a short (interim) report covering, as a minimum, dose and image quality, mechanical and radiation safety and any main items indicating whether or not the system should proceed to a practical evaluation. During this period of delay, preparatory work could be undertaken such as local physics testing, imaging specimens, testing connections with PACS, setting routine QC baselines and familiarising users with the equipment.

The equipment should only be used in a clinical setting once the technical evaluation has been successfully completed and any outstanding actions resolved. The manufacturer should confirm that the same model and software version is used for the technical and practical elements of the evaluation. A sign off checklist for the equipment and evaluation centre details is included in Appendix 1.

The project should only progress to the practical evaluation if the technical evaluation is satisfactory.

2.4 Trust awareness of the evaluation

If the equipment has been borrowed from the supplier for the period of the evaluation, it is important to have a local, formal agreement in place between the supplier and the host Trust to cover costs and liability. For example, some Trusts may require the evaluation project to obtain approval from the ethics committee or the novel procedures committee. The supplier must supply indemnity cover for the period of the evaluation.

2.5 Early termination of the evaluation

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

3. Workload and evaluation period

3.1 Throughput

The workload at the evaluation site should mirror the standard working practice at a screening centre or assessment centre (as appropriate). Recommended levels of throughput are given below, but these may need to be tailored for the equipment under evaluation. It is important to assess whether existing throughput can be maintained or increased using the equipment under evaluation, for example, by applying non-standard appointment times to some clinics. All evaluations should pay particular attention to any novel design features or modes of operating the equipment which may affect throughput.

3.2 Evaluation period

The evaluation period (not including installation and technical acceptance testing) should last a minimum of three months, but should not normally exceed six months. This should be adequate to provide an indication of the equipment's long term reliability and consistency of performance. Evaluation where the equipment is on a trailer should include at least one move during the evaluation period.

3.3 Evaluation of X-ray systems for mammography screening

Evaluators of mammography screening equipment should aim to examine over 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 and types should be covered (for example larger, denser breasts, women with implants).

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. Therefore, when the equipment has fully met the criteria for acceptable operational status, a number of full screening sessions should be arranged (a period of eight full days is suggested, with at least 50 women examined each day). This workload should not prove a problem at screening centres, but special arrangements may need to be made if the evaluation is performed at a centre that is primarily used for assessment.

Images from the first clinic should be carefully scrutinised by the clinical team and any concerns over image quality raised immediately with both the local physicist and the supplier. The national office and NCCPM must also be informed promptly of any such concerns.

The evaluation centre should record several clinics' worth of information to ensure that a full range of clients are included in the evaluation.

Radiologists/film readers should review a sample of at least 30 images on the reporting workstation, and record their assessment of image quality and ease of use (on Forms 8 and 9, Appendix 2). Radiographers should carry out a similar assessment of the acquisition workstation and images on it.

3.4 Evaluation of X-ray machines in an assessment setting

Evaluators should aim to examine at least 150-200 women on an assessment system, although numbers may be considerably higher at larger or busier centres. All of the equipment's modes of operation should be evaluated, including magnification and stereotactic operation where applicable. For the latter, both the adaptation of the equipment to stereotactic use and the operation of the equipment in the stereotactic mode should be investigated.

Where the stereo attachment is developed by the manufacturer at a later point, it should be subjected to a separate evaluation. An addendum to the original evaluation report should be written.

The minimum workload should be at least 25 magnification examinations and 10 stereotactic examinations. The magnification images should be evaluated in conjunction with the equipment's magnification function.

The evaluation period for assessment systems should be similar to that for screening systems. As with screening systems, the evaluation should cover a full range of breast sizes and densities and should include different types of lesions in different positions in the breast (for example, a spiculate lesion with calcification at the back of the breast).

3.5 Evaluation of other types of equipment for mammography

In future, there may be a requirement to evaluate other types of mammography equipment, such as prone biopsy systems and specimen X-ray cabinets. Clear objectives for these evaluations will need to be agreed between the national office, NCCPM and the evaluation centre.

When specimen cabinets are evaluated, a full range of specimen and lesion types should be imaged to ensure that the equipment's capabilities are fully examined. Satisfactory connection to PACS should also be demonstrated.

4. New technology

4.1 Evaluation of new technology

Any new technology with potential for use in the NHSBSP should be formally evaluated through the agreed equipment evaluation process. However, before any equipment is installed in the programme, evidence from trials and research should be considered by the Advisory Committee on Breast Cancer Screening. If an equipment trial is being set up in the NHSBSP, a full technical evaluation should be undertaken prior to clinical use of the machine.

4.2 Tomosynthesis

The evidence for the use of tomosynthesis in screening and assessment is still emerging.

If a review of the published evidence (from large studies or trials) by an expert group leads to approval for its use in assessment and/or screening, then each supplier's system should be evaluated formally by the NHSBSP. The protocols for practical evaluation of this technology will be agreed between the national office, NCCPM, and the evaluation site. Careful consideration will need to be given to the suitability of a site for a robust evaluation of the system.

As with other X-ray technology, systems using tomosynthesis must be judged to be satisfactory in terms of image quality and dose before being used in the NHSBSP. Formal standards and quality control protocols are currently under development.[3, 4]

4.3 Dual energy

When evidence for the use of dual energy systems becomes available, similar considerations to those outlined in section in 4.2 will apply.

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 (1999).[5] This will ensure that the safety features and warning devices operate correctly and that there is sufficient protection for persons from exposure to ionising radiation. The critical examination is customarily 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 quickly as possible.

5.3 Electrical and mechanical safety checks

These form an important part of the evaluation. The evaluation centre must ensure that the essential electrical and mechanical safety checks are carried out and that the outcome of these is reported appropriately. These checks can either be organised by the evaluation centre through the usual local channels, or by the local mammography physics service.

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 equipment. The physicists carrying out these checks must have appropriate experience. They should be trained in the testing of mammography X-ray equipment and should be routinely involved in work for the NHSBSP.

The physics test methods and protocols should broadly follow the procedures described in the latest edition of IPEM Report number 89[6] or the tests agreed for digital equipment.[7, 8, 9] 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.

Physics testing should include a dose audit, using patient dose calculation software provided to the NHSBSP by NCCPM.[10]

5.5 Technical evaluation by NCCPM

A full technical evaluation of the equipment will be performed by NCCPM. Suppliers will be required to complete a standard proforma (Appendix 3) before the technical evaluation is agreed. Representatives from the national office of the NHS CSP and NCCPM will then decide on the appropriateness of the evaluation for the NHSBSP.

A re-evaluation may be needed if equipment is found to be unsatisfactory when first assessed, or if the manufacturer makes significant changes to it after the initial evaluation but before the equipment is used. In such cases the proforma in Appendix 5 should be completed.

Evaluations of digital systems will be conducted with reference to NHSBSP guidance on the testing of digital mammography systems.[7] The technical 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 two to three days.

The draft report should be sent to the manufacturer/supplier for comment before publication. The equipment must not progress to a full practical evaluation until the technical evaluation has demonstrated that it meets the required NHSBSP standards.

6. Practical evaluation

6.1 Staffing

The practical 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 system and in the associated recordkeeping and data collation. Before the start of the practical evaluation, applications training should be provided by the supplier.

6.2 Record-keeping

Radiographers working on the system 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. PACS storage and archiving should be implemented.

Standard recording forms are provided in this document (Appendix 2). The forms may, by agreement, be modified for specific equipment or situations. The forms are also available separately on the NBSS website.

A record should be made of all faults and 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 reports should be completed for equipment undergoing evaluation and sent to NCCPM. Copies should be kept with the evaluation records.

Evaluation centres should be familiar with the equipment evaluation reports on similar equipment.

6.3 Project management and report of the evaluation

A site visit should be arranged before the evaluation starts. The local physicist and project lead should attend, as well as representatives from the national office and NCCPM. During the visit, these individuals should agree the objectives and timescales for the evaluation, and the eventual content of the evaluation report. Suppliers should provide details about the practical evaluation by completing the standard proforma provided in this document (Appendix 4).

Regular progress meetings should be arranged to discuss findings and agree timescales and reporting arrangements. Suppliers should be made aware of any shortfalls in equipment usage and performance at the earliest possible point. They

must be provided with the full draft report for comment at the end of the evaluation period.

The evaluation data must be collated and a report prepared for publication summarising the findings of the radiographers, the radiologists, and local physicists. The report should comment on the operation and specific features of the machine. It should also 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. Further guidance on writing the report is included in Appendix 6.

7. Image quality check and routine quality control measurements

7.1 Clinical judgement of image quality

Initial imaging of biopsy excision and mastectomy specimens should be undertaken. When the images have been judged by the lead radiologist to be of an acceptable standard, the system may be used for symptomatic cases, subject to all necessary local approvals being granted. The system may only be used for screening when it has been demonstrated that satisfactory results are being achieved.

7.2 Routine quality control

The routine quality control tests should comply with the guidance outlined in *Routine quality control tests for full field digital mammography systems*.[11] For new technology and other types of mammography equipment (for example, specimen cabinets) suitable quality control tests should be agreed at the planning stages.

8. Report preparation and publication

8.1 Preparing the draft

The project lead at the breast screening centre performing the evaluation will prepare the practical evaluation report. A report template and guidance on writing the report are given in Appendix 6. The report should be submitted in draft for review by the national office after completion of the practical evaluation.

The final outcome of the evaluation will be discussed with NHSBSP representatives, with the evaluation site (including the local Physicist), and with NCCPM. Together, they 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 it is published by the NHS CSP as an NHSBSP Equipment Report.

8.2 Publishing the report

The report will be made available on the NHS CSP website. Where necessary, the report may include a separate appendix with the supplier's responses to any problems identified.

References

1. Quality assurance guidelines for medical physics services (NHSBSP Publication No. 33, second edition). Sheffield: NHS Cancer Screening Programmes, 2005.

2. Quality assurance guidelines for mammography including radiographic quality control (NHSBSP Publication No. 63). Sheffield: NHS Cancer Screening Programmes, 2006.

3. Routine quality control for breast tomosynthesis (Physics) (NHSBSP Equipment Report 1407). Sheffield: NHS Cancer Screening Programmes, 2014.

4. Routine quality control for breast tomosynthesis (Radiographers) (NHSBSP Equipment Report 1406). Sheffield: NHS Cancer Screening Programmes, 2014.

5. The Ionising Radiations Regulations 1999 (SI 1999 No 3232). London: The Stationery Office, 1999.

6. The commissioning and routine testing of mammographic X-ray systems (IPEM Report 89). Institute of Physics and Engineering in Medicine, 2005.

7. Commissioning and routine testing of full field digital mammography systems (NHSBSP Equipment Report 0604, Version 3). Sheffield: NHS Cancer Screening Programmes 2009.

8. Recommended standards for the routine performance testing of diagnostic X-ray imaging systems (IPEM Report 91). Institute of Physics and Engineering in Medicine, 2005.

9. Assessment of display performance for medical imaging systems. *American Association of Physicists in Medicine* (AAPM On-line Report No 03, available at www.aapm.org/pubs/reports/OR_03.pdf), 2005.

10. Breast dose surveys in the NHSBSP: Software and Instruction Manual. Version 2 (NHSBSP Equipment Report 0405). Sheffield: NHS Cancer Screening Programmes, 2004.

11. Routine quality control tests for full field digital mammography systems - Fourth Edition (NHSBSP Equipment Report 1303). Sheffield: NHS Cancer Screening Programmes, 2013.

Appendix 1: Service Level Agreement

The Service Level Agreement should be completed before the evaluation starts. It must outline what is required from the centre for the evaluation, and will delineate the specific project objectives that have been agreed with the evaluation centre and NHSBSP national office.

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

SERVICE LEVEL AGREEMENT FOR THE EVALUATION OF DIGITAL IMAGING EQUIPMENT

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 1411), a copy of which has been provided to the centre undertaking the work.

2. **FEES**

   The NHSBSP will reimburse the cost of additional work undertaken by staff in the evaluation of a unit of mammography X-ray equipment, up to the maximum amounts stated below. The centre undertaking the evaluation will be responsible for the 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 report writing.

   2.1 For the preparation of a report (based on an evaluation protocol and data sheets provided by the NHSBSP) to assess equipment installed in a centre by arrangement with the NHSBSP for use by a centre that meets the eligibility criteria set out in the *Guidance Notes for Equipment Evaluation* (NHSBSP Equipment Report 1411), for the specific purpose of providing technical and practical information that will enable prospective purchasers in the NHS to determine its suitability for their intended application.

   Negotiable up to £10,000

2.2 For the preparation of a report (based on an evaluation protocol and data sheets provided by NHSBSP) on equipment installed and used by a centre, which meets the eligibility criteria set out in the *Guidance Notes for Equipment Evaluation* (NHSBSP Equipment Report 1411), for the benefit of the centre. Negotiable up to £2,000

2.3 For other equipment, for example, new stereo attachments, accessories and other ancillary equipment, lesser amounts will be as agreed with the centre before the start of this agreement.

Evaluation category (please circle) 2.1 2.2 2.3

Fee £

3. **PERSONNEL**

Names and contact telephone numbers should be provided.

Superintendent radiographer

Lead radiologist

Breast screening centre project leader

Breast screening centre physicist

NHSBSP project supervisor

4. **TIMESCALE**

Projected date of installation

Projected duration of evaluation

Projected date of first full draft report

Projected date of final draft

Date:

Signed: NHSBSP_____

Date:

Signed: B S Centre _____

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	Software version	
1.5	Evaluation centre details	
1.6	Breast screening centre project leader and telephone number	
1.7	Date of NCCPM technical evaluation	
1.8	Confirmation the equipment to be installed: 1. has appropriate connectivity to PACS and NBSS 2. is the same model and software version as was technically evaluated 3. has had all technical issues highlighted at the technical evaluation resolved (evidenced in a report from supplier)	

2. INSTALLATION

2.1	Date of start of installation	
2.2	Details of applications training staff	
2.3	What adjustments were required by local physicists	
2.4	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.	
2.5.	What adjustments were made to suit local radiographic requirements	
2.6.	Comment by engineer on adjustments made	
2.7	Date of acceptance for clinical use following a successful technical evaluation	
2.8	Date of start of practical evaluation	
2.9	Date of completion of practical evaluation	

3. DETAILS OF ACQUISITION AND REPORTING WORKSTATION

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

3.1	Manufacturer and type of acquisition and reporting workstations	ACQUISITION: REPORTING:
3.2	Number, manufacturer, type and resolution (pixel matrix) of monitors	ACQUISITION: REPORTING:
3.3	Software type and version	ACQUISITION: REPORTING:
3.4	Manufacturer and type of hardcopy device (if used)	
3.5	Resolution (pixel matrix) of hardcopy device	

4. TOTAL NUMBER OF EXAMINATIONS UNDERTAKEN

4.1	Number of excision specimens	
4.2	Number of mastectomy specimens	
4.3	Number of core biopsy specimens	
4.4	Number of symptomatic patients	
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	

Appendix 2: Digital equipment evaluation forms

Notes

Forms 1-12 should be used at appropriate stages of the evaluation.

Form 1: the information recorded can form the basis of the patient dose audit. Check the NCCPM data collection tool[10] at www.nccpm.org to ensure that all required data are collected. Where data can be downloaded automatically then this function may be used and it may not be necessary to complete this form.

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

Form 3: this form records exposure and image quality for stereo examinations.

Form 4: the fault reporting form available at www.nccpm.org should be used each time an equipment fault occurs (the form is not reproduced here). The original should be forwarded to NCCPM, and a copy should be kept with the evaluation data.

Form 5: this form gives one method of collecting data to enable the 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: this form should be completed by all radiographers using the equipment. Additional questions specific to magnifications and to stereos which are to be answered for these types of examinations are available at the end of the form.

Forms 7a to 7h: are the radiographic quality control forms. Further information on the tests themselves can be found in *Routine quality control tests for full field digital mammography systems.*[11]

Form 8: this form collects information on the user assessment of images. Alternative methods may be acceptable as long as comparable information is obtained and included in the report.

Form 9: this form should be completed by each film reader and radiologist using the reporting workstation.

Form 10: this form records exposure and image quality for specimen radiography.

Form 11: this form should be completed by all radiographers for tomosynthesis evaluations.

Form 12: this form should be completed by each film reader and radiologist using the reporting workstation for tomosynthesis evaluations.

NHSBSP equipment evaluation form 1: Exposure and image quality record – screening and assessment mammograms

Unit: Evaluation centre:

Exposure factors											Radiographer's comments	
Date	Patient ID	View	Field Size	Operation mode (AEC, autokV)	Dose indication or dose	Target/filter combination	kV	mAs	Comp thick (cm)	Comp force (N)	Comments on technical image quality at the acquisition workstation (blurring, contrast, noisy, artefacts, for example)	Initials

NHSBSP equipment evaluation form 2: Exposure and image quality record – magnification mammograms

Unit: Evaluation centre:

Exposure factors													Radiographer's comments	Film reader/radiologist's comments		
Date	Patient ID	View	Type of mag*	Mag factor	Field Size	Operation mode (AEC, autokV)	Dose indicator or dose	Target /filter combi-nation	kV	mAs	Comp thick (cm)	Comp force (N)	Comments on image quality (blurring, contrast, noisy, repeats, for example)	Clinical quality**	Comments	Initials

* Physical magnification (with mag platform) or high resolution mode ** Grade as excellent (E), good (G), satisfactory (S), poor (P)
Note: you may wish to collect further exposure data with different settings such as mA value
Images should also be viewed in optical magnification mode and compared with physical magnification.

NHSBSP equipment evaluation form 3: Exposure and image quality record – stereo examinations (use one line for each exposure)

Unit: Evaluation centre:

Exposure factors										Radiographer's/radiologist's comments		
Date	Patient ID	Projection	Operation mode (AEC, autokV)	Dose indication or dose	Target/ filter combi-nation	kV	mAs	Calibration checked?*	Initials	Clinical quality**	Comments for example, lateral arm used	Initials

* This should include a check of the measurement tool ** Grade as excellent (E), good (G), satisfactory (S), poor (P)

NHSBSP equipment evaluation form 5: Record of mammography sessions

Sheet number:
Unit: Evaluation centre:
Date: Assessor's name:
Was the operator working alone in the room? Yes/No
If no, what assistance was provided?
How long has the primary operator been involved in mammography screening in years?
Did the women change in the room or in a cubicle? Room/cubicle

Case number	Time taken from woman entering mammography room to woman leaving mammography room (minutes and seconds)			Woman's screen number? (1st, 2nd, 3rd?)	Compression paddle changes? (tick for yes)	Radiographer comments, for example, disability, discussion of clinical signs, large women requiring multiple images or other factors affecting time taken
	Start	End	Time			

Minimum number to collect = 2 full clinics' worth. An independent person should monitor times with a stop watch.

NHSBSP equipment evaluation form 6: Radiographers' observations and findings

A copy of this form should be completed by each operator, once comfortable with use and operation of the equipment

Unit: Evaluation centre:

Name:

	Excellent	Good	Average	Satis-factory	Poor	Comments
1. How good was the operator's manual?						
2. How good was the clinical applications training provided by supplier? Modality Workstation						
3. How do you rate the unit's ease of use?						
4. Were the X-ray exposure times acceptable?	Yes/No					(If not, explain – for example, hit backup timer frequently)
5. Setting for radiographic views: 5.1 How do you rate the rotation of the support arm? 5.2 How do you rate the visibility of the set angle?						

	Excellent	Good	Average	Satis-factory	Poor	Comments
6. How do you rate the facility for positioning the height of the breast support table?						
7. How adequate was the range of movements offered by the unit?						
8. Effectiveness of brakes/locks: How well did the brakes work? (was there any backlash or movement, for example)						
9. Suitability of environmental conditions required to use this equipment.						
10. Compression 10.1 How effective was the compression system? 10.2 Visibility of compression force from breast support table?						
11. How comfortable was the system for women?						Enter any informative comments made by women

	Excellent	Good	Average	Satis-factory	Poor	Comments
12. Range of controls and indicators: 12.1 Were all the expected controls present? 12.2 Were they easy to find and use?	 Yes/No Yes/No					Explain if no
13. How do you rate the choice of paddles/ collimators supplied for spot compression?						Assessment machines only
14. How do you rate the time for an image to appear at the acquisition workstation?						
15. How do you rate the image handling and processing facilities at the acquisition workstation?						Viewing examination, ease of swap between protocols, for example
16. How would you rate the overall image quality at the acquisition workstation?						
17. How easy was it to transfer images to the reporting workstation or to an encrypted hard drive, for example?						
18. What was your level of confidence in good results from the machine?						

	Excellent	Good	Average	Satis-factory	Poor	Comments
19. Were there any potentially hazardous areas accessible to: a. you? b. the woman?	 Yes/No Yes/No					Explain if yes
20. Equipment cleaning 20.1 Ease of cleaning the machine?						
20.2 Were there instructions in the manual?	Yes/No					
20.3 Does this meet the local Infection Control requirements?	Yes/No					
21. Was all necessary patient and exposure data available on the images?	Yes/No					
22. Did the digital X-ray system performance limit patient throughput?	Yes/No					If no, explain (for example, wait between exposures too long)

23. Any additional comments on general or imaging performance

Magnification

	Excellent	Good	Average	Satis-factory	Poor	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						

Stereo

	Excellent	Good	Average	Satis-factory	Poor	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. How do you rate the ease of rotational movement of the support arm with stereo assembly fitted?						
4. How easy is it to use is the stereo assembly?						
5. Comment on the accuracy of the needle positioning						
6. How would you rate the overall image quality of stereo images on this unit?						
7. How comfortable is this unit for women?						Please provide comments from the patients where possible

NHSBSP equipment evaluation form 7a: Daily and weekly system checks with Perspex blocks

Unit/Location, Model, Identifying Code

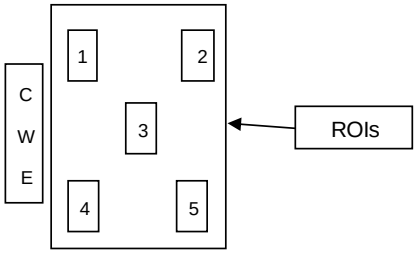
Add range of tolerances

Perspex (cm)		Compression paddle		Exposure mode	
Perspex size (cm)		Compression force		Image processing	

					Daily			Weekly				
Date	Detector temp (°C)	kV	Target/ filter	mAs	Pixel value (PV1)	Standard deviation (sd1)	SNR (PV1 / sd1)	Pixel value (PV2)	CNR (PV1-PV2) / sd1	Initials	Any visible artefacts?	Comments

NHSBSP equipment evaluation form 7b: Weekly uniformity test

Unit/Location, Model , Identifying Code



Perspex (cm)		Compression paddle	24 x 30
Perspex size (cm)		Compression force	
Exposure mode			
Image processing			

				Mean pixel value									
Date	kV	Target/ filter	mAs	ROI 1	ROI 2	Centre (ROI 3)	ROI 4	ROI 5	Any visible artefacts?	Comments	Initials	Max deviation from centre	(Limit 10%) Acceptable?

NHSBSP equipment evaluation form 7c: Monthly AEC thickness check

Unit/Location, Model, Identifying Code

Perspex size (cm)

Compression paddle

Compression force

Exposure mode

Image processing

Add range of tolerances

	2 cm								4.5 cm								7 cm									
Date	kV	Target/ filter	mAs	PV1	sd1	PV2	SNR	CNR	kV	Target/ filter	mAs	PV1	sd1	PV2	SNR	CNR	kV	Target/ filter	mAs	PV1	sd1	PV2	SNR	CNR	Initials	Comments

NHSBSP equipment evaluation form 7d: Scoring sheet for TORMAM

Breast Screening Unit						
X-ray unit						
Date of test						
Scorer						
TORMAM serial number						
Mode						
kV, target/filter						
mAs						
Monitor used						
Filament group 1						
Filament group 2						
Filament group 3						
Filament group 4						
Filament group 5						
Filament group 6						
Filaments total						
Particles 1						
Particles 2						
Particles 3						
Particles 4						
Particles 5						
Particles 6						
Particles total						
Contrast group 1						
Contrast group 2						
Contrast group 3						
Contrast group 4						
Contrast group 5						
Contrast group 6						
Contrasts total						
Grand Total						

NHSBSP equipment evaluation form 7e: Safety checklist

Year :	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Safety – check that:												
The emergency isolator functions correctly												
Powered movement of the table prevented when sufficient compression applied												
The automatic release of compression plate after an exposure functions correctly												
Automatic release override is functioning												
Emergency compression release operates correctly												
Compression force does not slip												
No sharp edges on machine surfaces												
No part of the system in direct contact with the woman becomes too hot												
Radiation warning lights on x-ray set and entrance to room operate correctly												
Function – check that:												
All movements are free running												
All mechanical/electromechanical brakes function properly												
Scale markings are clear on all linear and rotational movements												
All foot switches operate correctly												
All attachment locks function correctly												
Adequate light intensity from the light beam diaphragm												
Movement of compression plate is smooth												
Environment – check that:												
Room brightness less than 10 lux, no glare or light boxes illuminated												
Monitors clean												
Computer and hard drive fan clean and dust free												
Monitor - check that:												
Monthly SMPTE test pattern for acquisition monitor has been checked												
Initials and date												

NHSBSP equipment evaluation form 7f: Daily monitor tests (single monitor)

- Display a standard clinical mammogram or test pattern.
- Check under working conditions
    - Check for obvious faults such as gross distortion, artefacts
    - Check general condition - clean if necessary
    - Look at the text and lines on the screen – are they sharp and straight?
    - Check that its appearance has not changed significantly.
- Tick 2nd, 3rd and 4th columns if no problems.
- Note details of any problems, take action to get them corrected and initial below

Monitor…….. … **Location**……..……

Date	No obvious faults (distortion/ artefacts)	Text / lines sharp and straight?	Clean / good condition	Comments, for example, details of problem / action taken	Initials

NHSBSP equipment evaluation form 7g: Daily monitor tests (paired monitors)

- Display a standard clinical mammogram or test pattern.
- Check under working conditions
    - Check for obvious faults such as gross distortion, artefacts
    - Check general condition - clean if necessary
    - Look at the text and lines on the screen – are they sharp and straight?
    - Check that its appearance has not changed significantly.
- Tick 2nd, 3rd and 4th columns if no problems.
- Note details of any problems, take action to get them corrected and initial below

Workstation…….…….. … **Location**……..……

Date	No obvious faults (distortion/ artefacts)		Text / lines sharp and straight?		Clean / good condition		Comments, for example details of problem / action taken	Initials
	Left	Right	Left	Right	Left	Right		

NHSBSP equipment evaluation form 7h: Monthly tests of reporting monitors

Workstation ……

Location …… ……...……..

Date …… Initials ……

Room brightness less than 10 lux, no glare or light boxes illuminated	
Monitors cleaned	
Clean and dust all around computer and hard drive fan	

Display SMPTE test pattern on each reporting monitor

SMPTE test pattern	Monitor 1	Monitor 2	Comment
No significant reflections on monitor	Yes / No	Yes / No	
Borders are completely visible	Yes / No	Yes / No	
Lines are straight	Yes / No	Yes / No	
Active display area is centred on screen	Yes / No	Yes / No	
5% square visible in larger 0% square	Yes / No	Yes / No	
95% square is visible in larger 100%	Yes / No	Yes / No	
Each grey scale step (0% to 100%) can be distinguished from adjacent squares	Yes / No	Yes / No	
Text on pattern is sharp and in focus	Yes / No	Yes / No	
Line pair images in centre and all corners distinguishable	Yes / No	Yes / No	

NHSBSP equipment evaluation form 8: User assessment of digital image quality

Name of Assessor: Evaluation Centre:

Use the following letters as abbreviations when filling in the forms:

Breast composition:	Fatty (f), Mixed (m), or Dense (d)
Contrast:	Very high (VH), high (H), satisfactory (S), low (L), very low (VL)
Sharpness:	OK or blurred
Image noise :	OK or noisy
Suitability of image processing:	Excellent (E), good (G), satisfactory (S), poor (P), or inadequate (I)
Diagnostic value:	Excellent (E), good (G), satisfactory (S), poor (P), or inadequate (I)
Diagnostic value of zoom:	Excellent (E), good (G), satisfactory (S), poor (P), or inadequate (I)

Case Number	Screening Number	View used	Breast compo-sition	Overall contrast	Sharpness	Image Noise	Image processing	Diagnostic value	Diagnostic value of zoom	Comments
		cc								
		mlo								
		cc								
		mlo								
		cc								
		mlo								
		cc								
		mlo								

Summary:

	Excellent	Good	Satisfactory	Poor	Inadequate	Overall total
Total exams						
cc						
mlo						

NHSBSP equipment evaluation form 9: Workstation users' observations and findings, acquisition and reporting (if provided for the evaluation)

A copy of this form should be completed by each operator, once comfortable with use and operation of the equipment. Include any specific difficulties in the Comments column, and enter N/A where appropriate.

Unit: Evaluation Centre:

Type of workstation: Acquisition/Reporting

	Excellent	Good	Average	Satisfactory	Poor	Comments
1. How good was the operator's manual? (State if N/A)						
2. How good was the applications 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?						

	Excellent	Good	Average	Satisfactory	Poor	Comments
5. How do you rate the ease of use of the workstation controls? (Complete any applicable.) a. mouse/trackerball b. keyboard c. keypad						
6. How do you rate the image handling tools? (zoom, ruler)						
7. How do you rate the on-screen icons for: a. visibility? b. usability?						
8. How do you rate the post processing image manipulation (window and level)?						
9. How do your rate the reading/reporting flow-pattern?						

	Excellent	Good	Average	Satisfactory	Poor	Comments
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, that is, images performed beyond the standard four?						
12. How do you rate the time taken between an image or client being selected and appearing on the screen? a. new patient selection b. in-exam change						
13. How much of a problem was light from the database screen raising ambient lighting around the workstation?						
14. Did you identify any hazards associated with the workstation or its use?	Yes/No					
15. What is your overall level of satisfaction with the workstation?						

16. Describe any additional or unusual features or quirks of the system.

NHSBSP equipment evaluation form 10: Exposure and image quality record – specimen radiography

Unit: Evaluation centre:

Exposure factors									Radiographer's comments
Date	Patient ID	Type (excision, for example)	Field size	Operation mode (AEC, autokV, for example)	Target/filter combination	kV	mAs	Mag factor	Comments on technical image quality at the acquisition workstation (blurring, contrast, noisy, artefacts, for example)

NHSBSP tomosynthesis equipment evaluation form 11: Radiographer's observations and findings

A copy of this form should be completed by each operator, once comfortable with use and operation of the equipment
For each question, please tick one of the "Excellent to Poor" columns, and/or delete from the alternatives (Yes/No, Better/Same/Worse) as appropriate.

Equipment: Evaluation Centre:

	Excellent	Good	Average	Satis - factory	Poor	Compared with 2D	Comments
1. How do you rate the supplier's operator manual (if used)?						Better/ Same / Worse	
2. Did you prefer an in-house simplified version?	Yes / No						
3. How good was the clinical applications training for tomosynthesis provided by the supplier for : a. Modality? b. Acquisition Workstation?						 Better/ Same / Worse Better/ Same / Worse	

	Excellent	Good	Average	Satis - factory	Poor	Compared with 2D	Comments
4. How do you rate the unit's ease of use for tomosynthesis?							
5. How easy was it to attach/remove any special tomosynthesis device used with the X-ray equipment, for example, faceplate, bukky?							
6. How do you find carrying out the : a. special QA tests for tomosynthesis? b. calibration tests for tomosynthesis? c. Reporting workstation QA?	Difficult / Average / Easy Difficult / Average / Easy Difficult / Average / Easy						
7. Were the compression times acceptable for each exposure? (If not explain in comments)	Yes / No					Better/ Same / Worse	

	Excellent	Good	Average	Satis - factory	Poor	Compared with 2D	Comments
8. Did the unit performance limit patient throughput?	Yes / No					Better/ Same / Worse	
9. How do you rate the comfort of women during tomosynthesis exposures, including acceptability of gantry motion?							(Enter any informative comments made by women)
10. Range of controls and indicators (on-screen icons) for tomosynthesis:							
a. Were all the expected controls present?	Yes / No					Better/ Same / Worse	
b. Were they easy to find?	Yes / No					Better/ Same / Worse	
c. Were the icons easy to use?	Yes / No					Better/ Same / Worse	

	Excellent	Good	Average	Satis - factory	Poor	Compared with 2D	Comments
11. How do you rate the time for : a. an image to appear at the acquisition workstation? b. storage of the image? c. auto-deleting an image?						 Better/ Same / Worse Better/ Same / Worse Better/ Same / Worse	
12. How do you rate image handling at the acquisition workstation: a. scrolling through the image levels? b. the processing facilities? c. use of query/retrieve?						 Better/ Same / Worse Better/ Same / Worse Better/ Same / Worse	

	Excellent	Good	Average	Satis - factory	Poor	Compared with 2D	Comments
13. How easy was it to use, for tomosynthesis, the following (complete any applicable): a. keyboard? b. touchscreen? c. tracker ball? d. Wheel for scrolling through the tomosynthesis slices?						Better/ Same / Worse Better/ Same / Worse Better/ Same / Worse	
14. How do you rate the following: a. Image quality at the acquisition workstation for tomosynthesis images? b. Overall image quality of this system in tomosynthesis mode?							

	Excellent	Good	Average	Satis - factory	Poor	Compared with 2D	Comments
15. What was your level of confidence in the unit?						Better/ Same / Worse	
16. Were there any potential hazards with use in tomosynthesis mode to:							
a. you?	Yes / No					Better/ Same / Worse	
b. the woman?	Yes / No					Better/ Same / Worse	
17. Any additional comments on general or imaging performance in tomosynthesis mode							

NHSBSP tomosynthesis equipment evaluation form 12: Radiologists'/Readers' observations and findings

A copy of this form should be completed by each reader, once comfortable with use and operation of the equipment
For each question, please tick one of the "Excellent to Poor" columns.

Equipment: Evaluation Centre:

	Excellent	Good	Average	Satis-factory	Poor	Comments
1. How good were the operator manual instructions for tomosynthesis? (State N/A if not applicable/not used)						
2. How good was the application training for tomosynthesis provided by the supplier?						
3. Did you attend any external training course for tomosynthesis? If so, please enter Training Centre in the comments.	Yes / No					

	Excellent	Good	Average	Satis-factory	Poor	Comments
4. How do you rate the use of the reporting workstation controls for tomosynthesis? a. Mouse/trackerball b. Keyboard c. Keypad						
5. How do you rate the image handling tools (zoom, for example) for tomosynthesis?						
6. How do you rate the special tomosynthesis image handling tools such as slider or ciné?						

	Excellent	Good	Average	Satis-factory	Poor	Comments
7. How do you rate the visibility and usability of on-screen icons for tomosynthesis?						
8. Did you sometimes change the slab thickness when reviewing the tomosynthesis images?	Yes / No					
9. How do you rate the reading/reporting flow pattern in tomosynthesis?						
10. How do you rate the time for an image to appear on the screen in tomosynthesis mode? a. New patient selection b. In-examination change						

	Excellent	Good	Average	Satis-factory	Poor	Comments
11. How easy was it to record findings for tomosynthesis on NBSS?	Easy / Average / Difficult					
12. How easy is it to adjust the height and angle of the reporting monitors to suit the user?	Easy / Average / Difficult					
13. How easy was it to navigate between the tomosynthesis slices?	Easy / Average / Difficult					
14. How easy was it to set up different hanging protocols in tomosynthesis?	Easy / Average / Difficult					
15. How easy was it to change from one hanging protocol to another in tomosynthesis?	Easy / Average / Difficult					

	Excellent	Good	Average	Satis-factory	Poor	Comments
16. How do you rate the following properties of the tomosynthesis images? a. Contrast b. Sharpness						
17. What is your impression of the quality of images provided by the tomosynthesis system?						
18. What is your overall level of satisfaction with using this tomosynthesis system for assessments?						

19. Any additional comments on general or imaging performance of the system for tomosynthesis

Appendix 3: Proforma for a technical evaluation

This proforma should be completed by the supplier before a technical evaluation is arranged.

Please give full details as the information enables us to decide on the appropriateness of a NHSBSP technical evaluation at this time. It also helps us to plan the technical evaluation and work more efficiently.

Type of evaluation requested: (delete as appropriate)	Practical / both technical and practical (Note that a satisfactory NHSBSP technical evaluation is a prerequisite for a NHSBSP practical evaluation).
Supplier	
Manufacturer (if different)	
Model	
Software version	
Contact details for company representative: (name, title, email, phone)	
Possible site for technical evaluation? (to be agreed) When?	
Is the equipment CE marked?	
Is it market-ready, that is, no further modification / development expected in the near future?*	
Approx. number in use in Europe, rest of world?	

Has it been trialled in a busy screening environment for example, 10-12 women per hour?	
Clinical trials in progress / completed? Published?	
Technical evaluation already done by EUREF or another European country's testing body?	
Type of equipment: (delete as appropriate)	FFDM (2-D) / tomosynthesis / other (specify)
Type of detector, manufacturer	
Target and filter(s)	
Number of AEC modes. "Smart AEC"? (which detects dense areas)	
AEC mode provided where user selects kV, T/F and system determines mAs?	
Pixel size (µm)	
Detector size (mm)	
Available field size(s). Shifting paddle?	
Fine focus, mag table available?	
Biopsy unit available? (now or later?)	
Is the detector flat-fielded?	
"For processing" DICOM images readily available to physicists? (that is, without engineer assistance)	
Size of images (MB)	

Time from start of exposure to image appearing on AWS?	
Time from start of exposure to when next exposure can start?	
Please provide any other useful information and / or describe any special features not covered above (for example, tomosynthesis capability)	
Contact details for company representative: (name, title, email, phone)	
Signature and date	

*Note: If significant changes are made after the technical evaluation, and before the system is marketed, NCCPM will have to be reimbursed for the cost of any subsequent re-evaluation that is needed to ensure NHSBSP users have up-to-date information.

Appendix 4: Proforma for a practical evaluation

This proforma should be completed by the evaluation centre and by suppliers before a practical evaluation is arranged.

Please give full details as the information enables us to decide on the appropriateness of a NHSBSP practical evaluation at this time. It also helps us to plan the practical evaluation and work more efficiently.

Type of evaluation requested: (delete as appropriate)	Practical / both technical and practical (Note that a satisfactory NHSBSP technical evaluation is a prerequisite for a NHSBSP practical evaluation.)
Proposed centre for evaluation	
Contact details for evaluation team leader: (name, title, email, phone)	
Supplier	
Manufacturer (if different)	
Model	
Software version	
Possible installation date?	
Can the equipment link easily to the screening programme's Trust PACS and NBSS system for worklists?	
What level of technical support will the unit be given during the evaluation? Response to problems should be within 24 hours.	

What reporting workstation will be used and has this been set up optimally for mammography?	
Is it market-ready, that is, no further modification / development expected in the near future?	
Has the evaluation centre access to biopsy specimens/mastectomies for initial testing?	
Will it be evaluated in a busy screening environment, for example, 10-12 women per hour and will there be sufficient numbers?	
What clinical trials are in progress or completed? Please provide details	
Has a technical evaluation already been carried out by NCCPM, EUREF, or another European country's testing body? If so, please provide the report.	
Please provide any other useful information and / or describe any special features not covered above	
Contact details for company representative: (name, title, email, phone)	
Signature and date	

Appendix 5: Proforma for a technical re-evaluation

This proforma should be completed by the supplier before a technical re-evaluation of equipment not yet in use is arranged.

Please give full details, as the information enables us to decide on whether a NHSBSP technical re-evaluation is justified.

Supplier	
Manufacturer (if different)	
Model	
Software version	
Date of original technical evaluation	
Proposed date and site of re-evaluation	
Reason(s) for needing to repeat the technical evaluation (please explain in detail)	
Is the equipment NOW market-ready, that is, no further modification / development expected in the near future?	
Has the cost of the re-evaluation been agreed with NCCPM? If so, state cost agreed.*	

Any further comments	
Contact details for company representative: (name, title, email, phone)	
Signature and date	

*Note: If significant changes are made after the initial technical evaluation, before the system is marketed, NCCPM must be reimbursed for the cost of any subsequent re-evaluation that is carried out.

Appendix 6: Report writing

Equipment reports should be written in 12pt Arial. The less formatting that is used the better, as the document is reformatted completely by national office prior to publication. These reports will also be required to be in the PHE format.

Most equipment reports follow a template structure, and many sections can be written using standard wording. Referring back to an existing report can therefore be very helpful when writing a new document. Recent Equipment Evaluation reports are available on the NHSBSP website: www.cancerscreening.nhs.uk.

A6.1 Abbreviations

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

A6.2 Appendices

These should be used for details which do not sit comfortably in the text (for example, 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.

A6.3 Consistency

Please check carefully for consistency (for example in use of terminology, or use of abbreviations).

A6.4 Equipment manufacturer or supplier

Please double-check that you have used the correct name for the company. Any product information supplied by the company is usually copyright and can only be reproduced 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.

A6.5 Figures and tables

Please number tables and figures and cite them in order in the text.

A6.6 Headings

Main headings should be numbered sequentially. Sub-sections should be numbered 1.1, 1.2, 1.3 and so on. Any further subdivisions should be numbered 1.1.1, 1.1.2 and so on.

A6.7 Names of individuals/committees

Please check correct spelling (and correct contact details if these are given). Generally, individuals should only be named 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). Please ensure that details of all authors are provided.

A6.8 Report Content

The structure of a Technical Evaluation report should be as follows:

Section	Submission
Title page	Provide the title alone, which should follow the format 'Technical Evaluation of X'. Include software details where relevant (for example, *Technical evaluation of Hologic Selenia Dimensions 2-D with software version 1.4.2)*
Document details page	For submission purposes, provide names of the authors.
Version control sheet	Not needed for initial submission.
Contents page	Not needed for initial submission.
Acknowledgements page	Include details of anyone who needs to be thanked for their assistance.
Executive summary	This should be completed when the report conclusions have been finalised and should cover the main outcomes of the evaluation.
1. Introduction	Section 1.1 provides standard text on testing procedures and performance standards. Section 1.2 outlines the objectives of the evaluation, and lists anything that is not covered.
2. Methods	Section 2.1 provides more details of the system under test, including a standard table. A layout diagram or picture may also be provided.

	The rest of section 2 should describe how the system was tested in more detail, including but not limited to the measurement of: • output and half-value-layer (HVL) • detector response • AEC performance • noise analysis • image quality • image retention • physical measurement of detector performance • optimisation • artefact evaluation Where a test has not been conducted, this should be stated.
4. Results	Provide detailed results of the tests described in section 2. Graphs, tables, and figures should be included where appropriate. A comparison with other systems should be provided, with accompanying figures.
5. Discussion	Include a comment on whether performance of the system was satisfactory, and a summary of the major findings provided.
6. Conclusion	This should summarise whether the equipment is suitable for use in the NHSBSP.
7. References	These follow a standard format. Please consult a recent technical evaluation report for more details.

A Practical Evaluation report should cover the following:

Title page	Provide the title alone, which should follow the format 'Practical Evaluation of X'. (for example, *Practical evaluation of Hologic Selenia Dimensions digital breast tomosynthesis system*)
Document details page	For submission purposes, provide names of the authors.
Version control sheet	Not needed for initial submission.
Contents page	Not needed for initial submission
Acknowledgements page	Include details of anyone who needs to be thanked for their assistance.
Executive summary	This should be completed when the report conclusions have been finalised and should cover the main outcomes of the evaluation.
1. Introduction	Include a list detailing who conducted the physics testing, radiography and other activities.
2.Acceptance testing, commissioning, and performance testing	This should include a short explanation of the testing procedures and outcomes. Any installation issues and solutions can be included. The main results should be provided in an appendix, and an analysis of patient doses should be included.
3. Routine quality control	Describe what was undertaken and include graphs of the results.
4. Data on screening conducted	Provide details (for example, numbers screened, times), to describe how the clinics worked with the equipment installed.
5. Data on assessments conducted	Provide numbers assessed, and details of any use of magnification tables, stereo attachments and other equipment.
6. Equipment reliability	Provide information on the uptime of the unit, based on the number of hours for which it was actually in use over the total expected number of hours. Include important/significant points from the fault reports.
7. Electrical and mechanical	Include comments about the safety of the unit, including any van fixing kit used if the equipment was on a van. Details of

robustness	how it was moved, and of any installation and setup issues on site should be provided.
8. Radiographers' comments and observations	Include any comments about ease of use and any problems encountered. Comments on the ergonomics of the acquisition station and gantry can be included here.
9. Radiologists' comments and observations	Include a report from the radiologists/film readers on the practicalities of softcopy screen reading, use of tools, time taken to read, how previous films were handled, viewing conditions and other actions. Any conclusions relating to the workstations should be included here.
10.Confidentiality	Comment on how patient confidentiality was maintained.
11.Security issues	Comment on data security.
12. Training	Comment on the applications training that would be required to become proficient at using both the mammography equipment and the softcopy reading workstation.
13. Conclusions and recommendations	Draw together the conclusions and ensure that the objectives of the evaluation have been fully addressed.