



Department
of Health

NHS
England

Public health functions to be exercised by NHS England

Service specification No.24

Breast Screening Programme

November 2013

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Public health functions to be exercised by NHS England

Service specification No.24 Breast Screening Programme

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Department of Health

Contents

Contents.....	4
Service specification No.24.....	6
1. Background and introduction	7
Purpose of the Breast Screening Specification	7
Aims, objectives and health outcomes	7
Aims.....	7
Objectives	8
Common Health Outcomes.....	11
2. Scope of the screening programme.....	12
Description of the screening programme.....	12
In this section of the document, the following terms are used:.....	12
Activities Prior to Screening	12
Primary Screening	13
Assessment, diagnosis, referral, follow-up.....	14
Standards	15
Administration, audit, QA, failsafe, IT.....	15
Accreditation, training, guidance, research	16
Care Pathway.....	17
Failsafe arrangements.....	18
Roles and accountabilities.....	19
Commissioning arrangements.....	20
Links with the National Programme and ‘Do once and share’	20
3. Delivery of the screening programme	21
Service model summary	21
Population coverage	21
Programme Coordination	22
Clinical and corporate governance	22
Definition, identification, and invitation of cohort/eligibility	23
Location(s) of programme delivery	24
Days/hours of operation	24
Working across interfaces	24
Information on test/screening programme	25
Testing (performance of tests by individuals).....	26
Results reporting and recording	26

Providing results	26
Scope of cancer screening	26
Transfer of, and discharge from, care obligations	27
Exclusion criteria	27
Staffing	27
User involvement.....	28
Premises and equipment.....	28
Key Performance Indicators	29
Data collection and monitoring	29
Data reporting.....	29
4. Service standards, risks and quality assurance	30
Key criteria and standards.....	30
Risk assessment of the screening pathway.....	30
Quality assurance.....	30
Serious untoward incidents	31
Continual service improvement	32
5. Costs.....	33
6. Teaching and research activities	34
Appendix 1: Current National Minimum Standards for the NHSBSP	35
Appendix 2: High risk surveillance protocols	40
Appendix 3: Routine data requirements	43
Appendix 4: NHSBSP guidance not otherwise referenced	44
References	46

Service specification No.24

This is a service specification within Part C of the agreement 'Public health functions to be exercised by NHS England' dated November 2013 (the '2014-15 agreement').

The 2014-15 agreement is made between the Secretary of State for Health and NHS England under section 7A of the National Health Service Act 2006 ('the 2006 Act') as amended by the Health and Social Care Act 2012.

This service specification is to be applied by NHS England in accordance with the 2014-15 agreement. An update to this service specification may take effect as a variation made under section 7A of the 2006 Act. Guidance agreed under paragraph A38 of the 2014-15 agreement may inform the application of the provisions of this service specification.

This service specification is not intended to replicate, duplicate or supersede any other legislative provisions that may apply.

The 2014-15 agreement including all service specifications within Part C is available at www.gov.uk (search for 'commissioning public health').

1. Background and introduction

Purpose of the Breast Screening Specification

- 1.1. The purpose of this specification is to ensure that there is a consistent and equitable approach to the provision and monitoring of breast screening across England.
- 1.2. This document is designed to outline the service and quality indicators expected by NHS England to ensure that a high standard of service is provided to NHS England's responsible population. It therefore sets out the specific policies, recommendations, and standards that services are expected to meet.
- 1.3. The service specification is not designed to replicate, duplicate, or supersede any relevant legislative provisions which may apply, e.g. the Health and Social Care Act 2008, or the work undertaken by the Care Quality Commission. In the event of new guidance emerging, the specification will be reviewed and amended with as much rapidity as possible, but where necessary, both NHS England and service providers should work proactively to agree speedy variations of contract ahead of the production of a revised specification.
- 1.4. This service specification needs to be read in conjunction with the current NHS Breast Screening Programme (NHSBSP) guidance and recommendations. These can be found on the Cancer Screening Programmes (CSP) website: www.cancerscreening.nhs.uk

Aims, objectives and health outcomes

Aims

- 1.5. The major aim of the NHS breast screening programme is to reduce mortality from breast cancer. This will be achieved by delivering evidence-based, population-based screening programmes that:
 - identify the eligible population and ensure efficient delivery with optimal coverage
 - are safe, effective, of a high quality, externally and independently monitored, and quality assured
 - lead to earlier detection, appropriate referral, and improved outcomes
 - are delivered and supported by suitably trained, competent, and qualified, clinical and non-clinical staff who, where relevant, participate in recognized ongoing Continuing Medical Education, Continuous Professional Development, and EQA schemes

- have audit embedded in the service.

Objectives

Activities prior to screening

- 1.6. In accordance with good management practice and experience, in order to ensure appropriate and efficient use of NHS resources, the programme as a whole should¹:
- identify and invite eligible women for screening at appropriate intervals
 - provide the invited population with the information required, in the form in which it is required, so that women are able to make an informed choice about whether or not to participate
 - ensure that GPs are informed of screening in their area, and of the final outcomes of screening invitations for each of their patients
 - serve whole populations (all ages) numbering no less than 500,000 and up to about one million.

Primary Screening

- 1.7. The provider should:
- provide women who attend for breast screening with a high quality, effective, and people-centred service
 - carry out mammography in a way that minimises the possible adverse aspects of screening (e.g. radiation, discomfort, anxiety) and that maximises the benefits (i.e. detecting abnormalities at an early stage)
 - optimise attendance rates and maximise accessibility of the service for all groups in the community
 - use only equipment which meets the NHSBSP standards of image quality and radiation dose
 - allow women to opt out of the service, on a single occasion or permanently
 - provide adequate numbers of appropriately trained, qualified, and competent staff to carry out high-quality screening mammography
 - provide results within two weeks of attendance at screening for >90% of women.

Assessment, diagnosis, referral, follow-up

- 1.8. The provider should:
- undertake assessment and diagnosis of individuals with abnormal initial test results in appropriately staffed and equipped settings, at levels expected within the NHSBSP, and to the standards expected within the NHSBSP

- accurately diagnose cancers, with reference to MDT decisions, and refer women for treatment by appropriately trained and qualified specialists
- ensure that all women who undergo breast biopsies are discussed at a screening MDT
- ensure that assessment test results (whether normal, benign, or abnormal) are communicated clearly, accurately, and promptly, in person, by a member of the clinical team
- return individuals without breast cancer to routine recall as soon as possible
- minimise the number of women placed on short term recall, keep the number below the NHSBSP maximum level, and monitor this practice assiduously
- assess at least 90% of women within three weeks of attendance to screening.

Standards

1.9. The programme as a whole should:

- maximise the number of cancers detected
- minimise the number of cancers presenting between screening episodes
- maintain minimum standards of screening, whilst aiming for achievable standards (see Appendix 1)
- participate in both approved national routine audits and *ad hoc* audits to evaluate overall programme performance.

Administration, failsafe

1.10. The provider should:

- ensure effective and timely communication with the individuals who are invited, screened, assessed, or treated
- ensure effective and timely communication with the national office of the cancer screening programmes and Quality Assurance teams within Public Health England, clinical multi-disciplinary teams, other screening centres, NHS England, , the NHS Health and Social Care Information Centre, and the national office within PHE
- work within a seamless and integrated pathway
- apply NHSBSP failsafe guidance at all stages of the pathway
- ensure that the NHSBSP recommendations for handling incidents are adhered to, in addition to local reporting procedures.

Audit and Quality Assurance (QA)

1.11. The provider and the quality assurance team within Public Health England should work collaboratively to:

- regularly audit and evaluate the programme to ensure that the service is delivered in a safe, effective, timely, equitable, and ethical way, in accordance with national policy and NHSBSP standards, guidelines, internal and external quality assurance arrangements, and risk assessments
- monitor, collect, and report statistical data and other relevant information to relevant bodies, use it to promote continuous improvement in service performance and outcomes, give formal feedback to NHS England and the population served by the programme, and provide key information and models of good practice/innovation/achievement to those working in the area of breast screening

The provider should:

- participate willingly in multidisciplinary QA Visits organised by the cancer screening quality assurance team within Public Health England .

Information Technology (IT)

1.12. The provider should:

- use the programme's IT systems (NBSS and NHAIS) to manage women through the screening process, and to capture key screening data/outcomes promptly and accurately, supporting local and national QA and cancer registration processes and programme evaluation
- comply fully with local NHS CSP and NHS information governance requirements relating to the confidentiality and disclosure of patient information and system/information security.

Accreditation, training, guidance, research

1.13. The provider should:

- ensure that staff are appropriately trained and supported by national continuing professional development and skills frameworks, enabling them to develop their skills, competencies, and potential. Only approved/accredited training courses should be used, and these should be funded locally
- contribute to nationally-approved research into the screening and diagnosis of breast cancer, to inform screening practice and policy
- ensure that all pathology laboratories dealing with screening programmes are formally accredited by UKAS or equivalent

- ensure readers and pathologists reporting images and material participate routinely in PERFORMS and EQA schemes.

Safety and Safeguarding

- 1.14. The provider should refer to and comply with the safety and safeguarding requirements as set out in the NHS Standard Contract.

Common Health Outcomes

- 1.15. The programme as a whole aims:
- to reduce the number of women in the target population who die from breast cancer by 20%
 - to maximise detection of breast cancer at stages 1 and 2 (PHE domain 2)
 - to refer women promptly to treatment services
 - to achieve high coverage levels across all groups in society
 - to minimise adverse physical/psychological/clinical aspects of screening (e.g. anxiety, unnecessary investigation)
 - to encourage early presentation of symptomatic cancers, which may develop between screening episodes.

2. Scope of the screening programme

Description of the screening programme

In this section of the document, the following terms are used:

- **NHSBSP** This describes the entire programme, from identifying individuals to be invited to referral for treatment/return to routine screening as applicable
- **Breast screening unit** There are 80 breast screening units in England, which are responsible for the delivery of breast screening programmes locally to a defined population.
- **Provider** This is the NHS Trust or private provider that is contracted to provide screening centre activities. If a breast screening unit comprises more than one provider, one will be the lead and hold the contract with NHS England
- **Eligible population** Women are eligible for screening if they are in the screening age range or in a specified high risk category and are not ineligible due to bilateral mastectomy.

Activities Prior to Screening

2.1. In accordance with agreed management and professional best practice shown in Appendix 1, the provider should:

- invite women who move into the screening catchment area, or who are registered with a GP in the screening catchment area, to attend for screening before their 53rd birthday. (This becomes their 50th birthday if they are included in the programme extension trial)
- ensure that women who have already attended for screening are offered screening again within 36 months of their previous screen until they reach the age of 71
- enable those who have received their final routine invitation to continue to be screened at 3-yearly intervals on request or as part of the programme extension trial
- ensure that women who are not on NHS lists have access to screening, and that local arrangements are made to cover residential institutions, including prisons
- contribute to optimising acceptance by liaison with GP practices (by visiting, telephone call, or in writing) and by providing practices with up-to-date information about the Programme
- ensure that referrals for high-risk screening are only taken from specialised services e.g. Genetics or Oncology. The screening programme is not expected to carry out risk assessments for these cases

- ensure that screening is provided to women who are eligible for higher-risk breast screening to NHSBSP protocols and standards.

Primary Screening

2.2. The provider should:

- encourage attendance by ensuring that the process of changing appointments is straightforward for those women who request this
- invite women who are eligible for higher risk breast screening to be screened with appropriate modalities, at appropriate ages and intervals, according to NHSBSP protocols.
- send women who do not attend a second appointment letter, with a timed appointment
- encourage women to request screening if they are over the age where routine invitations are sent, and have not received an invitation as part of the age-extension trial
- keep supporting documentary evidence for any woman who is ceased from the programme for an indefinite time period. This information should be held by the screening service which would otherwise be responsible for her screening
- routinely cease only those women who have had bilateral mastectomies
- carry out annual audits on ceased women
- develop and regularly review a screening Round Plan to ensure that the appropriate population is covered and that invitations are sent promptly, in accordance with the timescales outlined above
- deal with women who request to be screened or assessed at an alternative screening centre according to agreed systems and protocols
- send results of basic screening to the woman within two weeks of her screening attendance
- enter only women who meet the criteria for high risk into the NHSBSP high-risk screening programme.
- ensure that image quality and radiation dose are optimised, with technical repeats minimised
- ensure that all equipment used complies with national equipment standards, and is tested routinely by appropriately trained staff and medical physics services, in accordance with NHSBSP guidelines

- ensure that all mammography X-ray systems used in the screening programme are Full Field Direct Digital Mammography systems, and that image quality and radiation dose meet acceptable standards
- ensure that staff working in the programme are trained to meet the required standards of competence and are actively involved in continuing personal and professional development.
- ensure that all screening examinations are acquired using full-field digital systems and are subject to double reading

Assessment, diagnosis, referral, follow-up

2.3. In accordance with NHSBSP standards and protocols, the provider should:

- refer for assessment women with significant mammographic or MRI abnormalities, or significant screen-detected breast cancer signs or symptoms
- offer women an appointment to an assessment clinic within three weeks of their initial screen.
- notify women in writing of their assessment clinic appointment and ensure that they have at least 24 hours notice of the appointment
- provide those attending follow-up appointments with clear information about the assessment process
- ensure all women attending a follow-up appointment have access to a breast cancer nurse
- utilize triple assessment for further investigations (needle test/ additional imaging/ clinical examination)
- ensure that biopsy specimen imaging is available whilst the woman is still positioned in the stereo X-ray equipment
- discuss all women undergoing biopsy at a multidisciplinary team meeting
- notify women and their GPs of the outcome of assessment. Results should be reported to the women in person, with a member of the clinical team present
- refer women for open surgical biopsy, if this is necessary to confirm or exclude malignancy, before discharge or onwards referral from the programme
- carry out localisations only in facilities that meet the NHSBSP standards
- ensure that results of assessment are reported to the woman in person, by a member of the clinical team. Cancer diagnoses should be provided by the clinician leading the care of the woman

- ensure adequate equipment and staffing levels are in place so that women can be fully assessed in the course of a single visit wherever possible (repeat assessment visits should be kept to a minimum)

Standards

2.4. In addition to meeting the minimum standards in Appendix 1, the provider should:

- ensure that all staff working in the NHSBSP are familiar with relevant and current QA guidelines
- ensure that all staff maintain minimum standards, and also adhere to NHSBSP guidance and recommendations via internal audit and external quality assurance monitoring
- take prompt action where standards are lower than expected to identify the causes and improve the service
- agree early warning systems and triggers with the local quality assurance team within Public Health England
- manage serious failures to provide services to the level specified in the NHSBSP QA guidelines according to NHSBSP protocolsⁱⁱ
- ensure that all programmes have a multidisciplinary QA visit at least once every three years
- use nationally developed and agreed letters and leaflets.

Administration, audit, QA, failsafe, IT

2.5. The call/recall database used by the NHSBSP is the National Health Application Infrastructure Services (NHAIS) system, often called the 'Exeter system'.

Although this is a national system, it is operated as about 80 separate local databases and maintained by local call and recall offices. These offices were previously referred to as 'family health service authorities', but their responsibilities passed to primary care trusts (PCT) and have now transferred to NHS England.

2.6. The Exeter system is able to perform numerous data searches, referred to as 'analysis jobs', which can identify individuals that fall within certain set criteria. Batches of eligible women are called from the NHAIS system by the screening programmes. Regular failsafe batches are requested by the breast screening offices to ensure that no individual is missed. In addition, women who have had a bilateral mastectomy, or who request cessation from screening are ceased from this system to ensure that they no longer receive invitations for screening. An annual audit of the NHAIS system is undertaken, and implementation of recommendations reported by the quality assurance coordinator

2.7. Results of breast screening are automatically sent from the NBSS system to the NHAIS system to determine future call/recall management. The system runs national returns showing screening coverage (KC63).

2.8. The provider should:

- utilise the NHAIS/NBSS system to ensure that coverage is optimised and the care pathway is managed to its planned conclusion
- specify failsafe batches and run these at least once every three months to ensure that all eligible women are invited
- maintain, comply with, and regularly audit the Quality Management System and accompanying documentation. This will ensure that the right results are given, that the screening pathway is safe and seamless, that incidents are minimised, and that the programme's performance is optimised. The screening process should be entered into the IT system according to NHSBSP protocols (including direct entry of results) and the 'Right Results' audit should be undertaken annually, with compliance demonstrated at QA visits
- ensure that all clinicians audit their own work in comparison to their peers and that they demonstrate a willingness to alter their practice if the outcome reveals this to be necessary
- subject to particular review the preceding screening episode, where a woman is subsequently diagnosed with an interval breast cancer
- work with staff from the quality assurance team within Public Health England to identify, and categorise, interval cancers and enter these onto NBSS in a timely manner
- review, on an annual basis, the number of women who have requested screening or assessment at an alternative service
- provide statistical analyses of uptake and coverage, and of individual, professional and team performance on request to both NHS England and quality assurance teams within PHE.

Accreditation, training, guidance, research

2.9. The provider and the quality assurance team within Public Health England should:

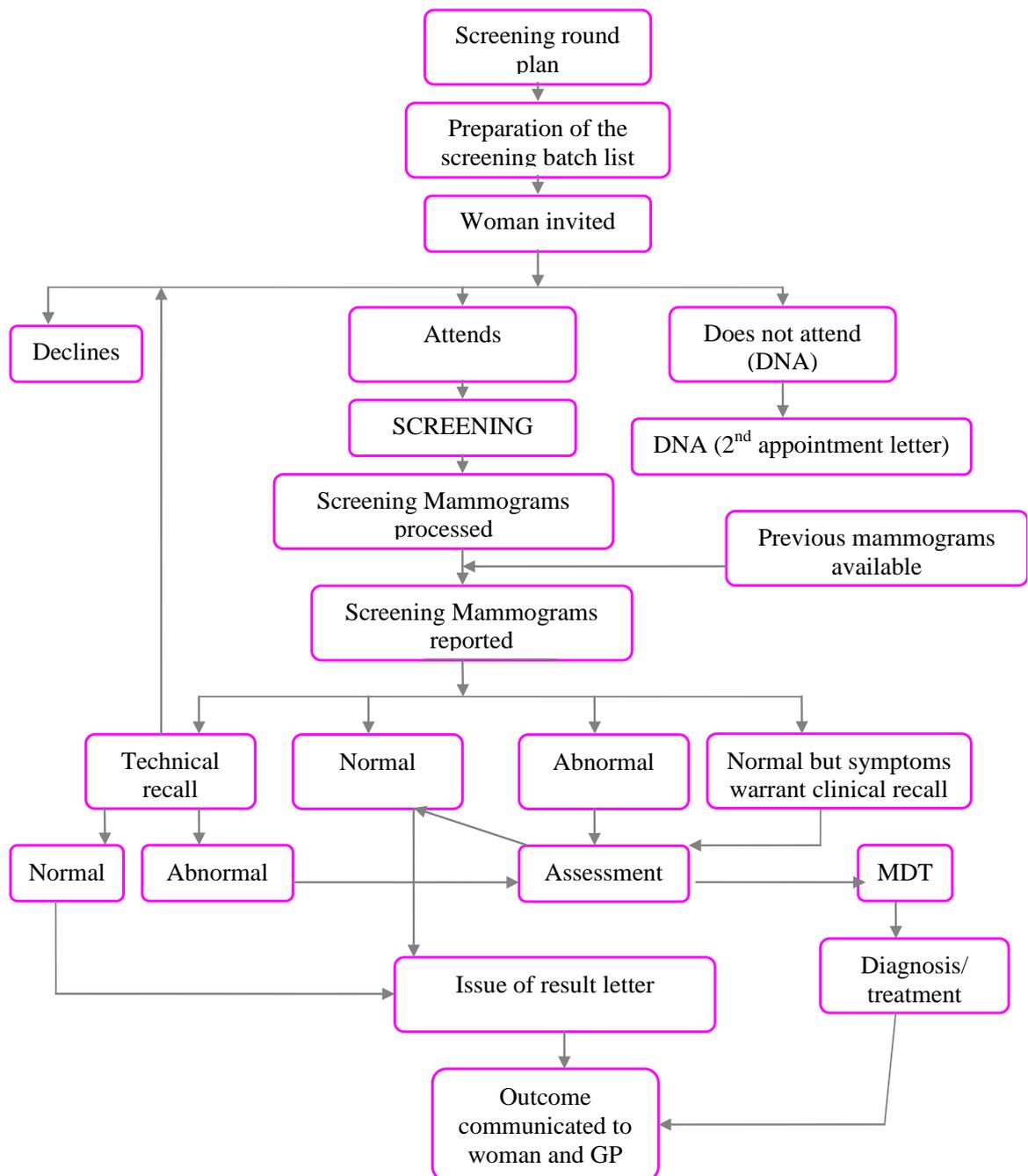
- ensure that all screening service staff regularly participate in quality assurance activities (including 3-yearly QA visits, the EQA scheme (pathologists), PERFORMS (film readers) and that all professionals meet CPD/CME requirements

The provider should:

- encourage eligible women to participate in appropriate clinical trials or studies.
- ensure that only CPA accredited labs are used for analysis of breast tissue material

Care Pathway

2.10. The flow diagram on the following page shows the pathway from development of a three year plan to the final outcome of the screening examination.



Failsafe arrangements

2.11. Quality assurance within the screening pathway is managed by the inclusion of failsafe processes. Failsafes are a back-up mechanism, designed to ensure that, where something goes wrong, processes are in place to identify: what is going wrong; and what actions are necessary to ensure a safe outcome.

2.12. The provider is expected to:

- include appropriate failsafe mechanisms across the whole screening pathway. Details of appropriate procedures are embedded in the guidance and recommendations on the NHSBSP's website (See, for example, the advice on second appointments, *Right Results*, MDT discussion of all needle tests, and the running of regular failsafe batches)
- review and risk assess local screening pathways in the light of guidance offered by Quality Assurance processes or the national office (PHE)
- work with NHS England and quality assurance teams within PHE to develop, implement, and maintain appropriate risk reduction measures
- ensure that mechanisms are in place to regularly audit implementation of risk reduction measures and report incidents
- ensure that appropriate links are made with internal provider governance arrangements, such as risk registers
- ensure routine staff training and ongoing development take place.

Roles and accountabilities

2.13. The breast screening programme depends on systematic, specified relationships between screening services and stakeholders (which include treatment services, the laboratory, genetics services, external diagnostic services, Primary Care representatives, etc). The provider will be expected to take the lead in ensuring that inter-organisational systems are in place to maintain the quality of the whole screening pathway. This will include, but is not limited to:

- providing coordinated screening across organisations, so that all parties are clear about their roles and responsibilities at every stage of the screening pathway, and particularly where responsibility for a patient is transferred from one party to another
- developing joint audit and monitoring processes
- agreeing joint failsafe mechanisms, where required, to ensure safe and timely processes across the whole screening pathway
- contributing to any initiatives led by NHS England or Public Health England to develop the screening pathway in line with the NHSBSP expectations
- maintaining robust electronic links with IT systems and relevant organisations across the screening pathway
- agreeing links with primary care, and with secondary and/or tertiary care.

Commissioning arrangements

2.14. Breast screening services will be commissioned by NHS England alongside specialised commissioning of cancer services. Minimum data requirements for NHS England are shown in Appendix 3.

Links with the National Programme and 'Do once and share'

2.15. Certain functions of English national cancer screening programmes are managed from PHE by the national office of the cancer screening programmes. National guidance documents can be accessed via the NHSBSP websites.

3. Delivery of the screening programme

Service model summary

- 3.1. In accordance with the national standards, the service will provide all necessary steps required to diagnose or exclude breast cancer. This includes breast screening mammography and subsequent assessment for those women who require recall after their initial screen, and open biopsy (where required). Screening a woman identified to be at high risk of breast cancer may involve MRI.
- 3.2. The screening programme will be offered to eligible women at a maximum interval of 36-months, according to the criteria specified by the NHSBSP. Screening of women will commence within three years of the specified starting age.
- 3.3. All women registered with a GP in the catchment area, and those resident in the area without a GP but eligible for NHS care, are included. Particular arrangements will be made for women in border areas who have Scottish or Welsh GPs. The service will invite women aged from 50 to 70 years of age. It will screen women aged 71 or over who self-refer every three years.
- 3.4. Women who have been assessed by specialised services and categorised as having a higher risk of developing breast cancer, and who meet the eligibility for screening within the NHSBSP will be included in the screening programme at a younger age and according to different protocols, following an appropriate referral from a Genetics or Oncology service.
- 3.5. There must be seamless links between 'screening responsibility' and 'treatment responsibility', so that women at the end of the screening process are referred to treatment services, once diagnosis with breast cancer is made explicit.
- 3.6. All elements of the screening pathway must be delivered by appropriate staff, to national standards and guidelines.

Population coverage

- 3.7. NHS England and screening service providers will work together to:
 - ensure that up-to-date population registers and lists of GP registered populations are maintained and cleaned to guarantee accuracy and completeness
 - optimise coverage and uptake across their catchment area
 - cooperate with regular analysis of breast screening coverage to identify groups of women who either access breast screening at lower levels, or do not access services at all

- deliver screening and assessment from agreed accommodation, which is appropriate to house the equipment needed for full-field digital mammography (FFDM), and ensure that the number and location of pieces of screening equipment meet the needs of the resident screening population and also national and regional screening guidelines
- 3.8. NHS England will provide annual estimates of the eligible population for at least three years ahead, based on the current population database.

Programme Coordination

The provider will:

- be responsible for ensuring that the programme it delivers is coordinated. Where collaboration is necessary, each part of the programme should interface seamlessly with others, particularly in the areas of timeliness and data sharing. This will ensure that the aims and objectives of the NHSBSP are met.
- ensure that one or more named individuals are responsible for the coordination of planning and delivery. This individual should be given appropriate administrative support to ensure timely reporting and response to requests for information.
- ensure that a Programme Manager and a named Director of Breast Screening are appointed. Both must be actively involved in the screening programme, and the latter must be a medically qualified clinician who will take overall responsibility for the service and its quality. Both the Director and the Programme Manager must be given adequate resources to carry out their roles effectively.
- ensure that adequate cover arrangements are in place to guarantee the sustainability and consistency of the programme.
- meet with NHS England at regular intervals (at least annually). The meetings will include representatives from programme management, clinical services, laboratory services, and service management.

Clinical and corporate governance

3.9. The provider of breast screening will:

- ensure that staff cooperate with, and are represented on, the local screening oversight arrangements/ structures: this might include the local office of NHS England and local authority Health and Wellbeing Boards
- identify responsibility for the screening programme at Trust Director level, or delegated responsibility
- ensure that there is appropriate internal clinical oversight of the programme's management, and that internal governance is overseen by both a Clinical Lead (the Director of Breast Screening) and a Programme

Manager, who will establish regular screening multi-disciplinary team meetingsⁱⁱⁱ

- regularly monitor and audit the screening programme as part of organisation's clinical governance arrangements, thus assuring the organisation's board of the quality and integrity of the service
- comply with NHSBSP guidance on managing serious incidents^{iv}
- put appropriate arrangements in place to refer individuals to appropriate treatment services in a timely manner
- provide evidence of clinical governance and effectiveness arrangements on request
- report annually to the Trust board on the performance of the local breast screening service. The report should identify areas of difficulty and plans to address these.^v Annual reports should be made available to the quality assurance director.
- have a sound governance framework in place covering the following areas:
 - information governance/records management
 - equality and diversity as defined by the Equality Act 2010
 - user involvement, experience and complaints
 - failsafe procedures
 - communications
 - ongoing risk management
 - health and safety
 - insurance and liability.

Definition, identification, and invitation of cohort/eligibility

3.10. The target population to whom screening is to be offered comprises all women in the eligible age group who are registered on specified NHAIS systems with specified GPs, or who are resident in the specified area and not registered with the NHS in England but entitled to NHS care.

3.11. Additionally, women are eligible for high-risk screening if they are referred from Genetics or Oncology services, and meet agreed criteria. screening programmes are not expected to carry out risk assessments and will not take direct referrals from GPs.

3.12. The target age group for routine screening is 50-70. Women who do not attend their offered appointments can subsequently refer themselves to the programme, and should be screened.

3.13. The provider will

- ensure that women not routinely invited over the age range can continue to be screened every three years.

- make every effort to maximise screening uptake from vulnerable and hard-to-reach groups within the eligible population.

Location(s) of programme delivery

The provider will

- ensure that screening takes place in suitable and appropriate mobile or static locations, which take account of the public transport links and car parking arrangements.

Days/hours of operation

3.14. The days and hours of operation will be locally determined and suitably accessible for the target population. However, timeliness of screening and assessment is essential, and this is a key criterion of quality along all parts of the screening pathway. The provider should therefore be able to:

- demonstrate efficient and effective use of resources.

Working across interfaces

3.15. The screening programme is dependent on strong working relationships (both formal and informal) between the professionals and organisations involved in the screening pathway. Accurate and timely communication and handover across these interfaces are necessary to reduce the potential for errors and ensure a seamless pathway for service users. The provider will

- Ensure that there are clear, named lines of clinical responsibility at all times, and particularly where there is handover of care.
- State these lines of clinical responsibility in an operational policy within the programme.

3.16. The provider will ensure that appropriate systems are in place to support timely and seamless referral to treatment services, including but not limited to:^{vi}

- agreeing and documenting roles and responsibilities relating to all elements of the screening pathway across organisations
- providing strong clinical leadership and clear lines of accountability.
- developing joint audit and monitoring processes
- working to agreed NHSBSP standards and policies
- agreeing jointly, between all agencies, on the failsafe mechanisms that are required to ensure safe and timely processes across the whole screening pathway
- meeting the screening programme standards set by the national office of the NHS Cancer Screening Programmes within Public Health England

3.17. The provider must ensure that procedures at interfaces follow these guidelines:

- invitation and reminder letters should be sent to women with timed appointments
- where women do not attend a first appointment, a second timed appointment should be sent by letter
- a Radiographer/ Assistant Practitioner should provide diagnostic quality mammograms to the expert readers and must meet NHSBSP standards for training and experience
- readers should recall appropriate women for further assessment
- office staff should send letters to recall women for further assessment and to deliver normal results
- women called back to assessment should have access to a clinical nurse specialist at any point during their assessment appointment
- women should be given the results of their assessment in person by appropriately trained clinical staff in the most appropriate format to meet their needs
- a failsafe system should ensure laboratory receipt of correctly identified needle samples
- the laboratory service should provide timely results to the screening MDT, to facilitate decision making
- MDT outcomes should be accurately recorded on the breast screening IT system
- GPs should be informed of screening attendance and outcomes for each of their patients
- Symptomatic services should inform screening services about interval cancers
- Genetics services should send only appropriate referrals as specified in higher-risk breast screening guidance and should be informed of screening outcomes after each subsequent attendance

3.18. In addition, see section in Chapter 2 on the Care Pathway.

Information on test/screening programme

3.19. The provider will

- ensure that, at relevant points throughout the screening pathway, women are provided with approved information on breast screening and breast cancer treatment.

- ensure that a trained interpreter is available during appointments for women whose functional language is not English, along with appropriate written information
- provide appropriate support for women with physical disabilities
- ensure that women with learning disabilities are provided with support to enable them to understand all processes and results

Testing (performance of tests by individuals)

3.20. The provider will ensure that

- screening units follow policy guidance and standards for screening mammography (and MRI, where appropriate).
- screening units enter routine data onto the National Breast Screening Information System (NBSS) in a timely manner and in the required format, as specified in NHSBSP manuals and guidance.

Results reporting and recording

3.21. The provider will ensure that

- All images from the initial screening examination are reported directly onto the NBSS system promptly by the reader who is directly responsible for those results.
- The Programme records conclusive results on the information system for the whole screened population.

Providing results

3.22. The provider will ensure that

- women are notified of a normal result from the screening process within two weeks of the initial examination by letter, and that their GP is also informed.
- the results of needle tests undertaken at an assessment visit are given by a clinician.
- A Clinical Nurse Specialist will be available to support the women as required after a benign diagnosis or a diagnosis of cancer.

Scope of cancer screening

3.23. The NHSBSP includes all investigations necessary to confirm or rule out a diagnosis of breast cancer.

Transfer of, and discharge from, care obligations

3.24. The screening programme covers the period from identification of the eligible population to diagnosis. Women who receive a diagnosis of breast cancer will continue to receive invitations for screening if they remain eligible. The provider should:

- advise women who have received a diagnosis of breast cancer to contact the screening office for advice about screening in their particular case.
- transfer women efficiently to treatment services on diagnosis. Any post-treatment follow-up will be the responsibility of the treatment service.

Exclusion criteria

3.25. This specification does not include the following activities, or any work or cost associated with them:

- Women below the current eligible age group (unless they meet the high-risk criteria)
- Women who are not eligible for NHS care
- Women who have had bilateral mastectomy
- Symptomatic referrals
- Post diagnosis follow-up and management
- The treatment of breast cancer
- Women who do not meet the criteria for higher-risk screening within the NHSBSP.

3.26. See Clause 54 of *The Standard Terms and Conditions for Acute Hospitals* (Gateway Reference 15458) for the contractual requirements for equity of access, equality, and the avoidance of discrimination.

Staffing

The provider will

- ensure that there are adequate numbers of trained, qualified, and competent staff in place to deliver a high-quality breast screening programme, in line with best practice guidelines and NHSBSP national guidance.
- ensure that all staff demonstrate competence in their area, linked to training (qualifications will be specific to the groups of staff delivering the service across the care pathway).

- have in place a workforce plan designed to maintain a sustainable programme, especially where an increase in the eligible population is predicted (generally this is the case until 2027) and/or where there are difficulties in the recruitment of appropriately qualified healthcare staff.
- ensure that professionals involved in the NHSBSP screening programme are aware that they are required to keep up-to-date with nationally approved training programmes and CPD/CME etc. and to participate in educational schemes such as PERFORMS and histopathology EQA as appropriate.
- ensure that arrangements are in place so that Assistant Practitioners are given adequate clinical supervision by a registered healthcare professional who is working with them in the imaging or treatment room or immediately accessible for support and advice (telephone supervision is not appropriate). Providers must ensure that all Assistant Practitioners are working within the national Scope of Practice

User involvement

3.27. In accordance with good practice, to gain feedback on services provided, and to have public involvement on service provision, the provider will collect the views of service users will often be via surveys or questionnaires. It is expected that such surveys will take place on a regular (rather than ad hoc) basis and that the results will be made available to NHS England. The provider will :

- demonstrate that they have collected (or have plans in place to collect) the views of service users, in respect of the services they provide
- demonstrate how those views will influence service delivery for the purposes of raising quality
- show that all women are given information about how to provide feedback about services they receive, including the complaints procedure.
- Working instructions must be developed which detail the roles and local scope of practice for radiographers, assistant practitioners, and advanced practitioners

Premises and equipment

3.28. The provider will ensure that:

- suitable premises and equipment are provided for the screening programme
- only mammography equipment evaluated by the NHSBSP is used for screening

- full-field direct digital mammography is the only modality used for routine screening. MRI may be used for higher-risk women according to NHSBSP protocols
- MRI screening is only carried out by services that meet the MRI Technical Guidelines developed by the NHSBSP
- only technologies and protocols that have been evaluated and recommended by the national office of the Cancer Screening Programmes within PHE are used in the programme, and that the manner of their use accords with national guidelines. The provider must make all staff aware that unorthodox use of approved technologies or used of unapproved technologies is prohibited within the NHS Breast Screening Programme, except as part of a formal national pilot, or a properly constituted and approved research project. The definition of 'technology' here is an inclusive one, but normally refers to mammography equipment.
- appropriate policies are in place for equipment calibration, maintenance, and replacement
- the NBSS database is able to support the programme and to supply data for the purpose of national standards and Key Performance Indicators
- failsafe routines are run on NBSS.

Key Performance Indicators

3.29. The provider will adhere to the requirements specified in Appendix 1.

Data collection and monitoring

3.30. The provider will

- provide routine data to NHS England, Public Health England and the Health and Social Care Information Centre in a timely manner.
- contribute to national data collection exercises where required
- provide annual data measuring performance against both standards and the Key Performance Indicators

Data reporting

3.31. The provider will

- report data to NHS England and Public Health England on a quarterly and annual basis. Appendix 3 shows routine data requirements
- participate in data reporting for consolidated annual reports KC62 (activity) and 63 (coverage), currently published by the Health and Social care Information Centre for the purpose of service comparison.

4. Service standards, risks and quality assurance

Key criteria and standards

4.1. Providers must

- meet at least the minimum standards found in Appendix 1, and strive for the achievable standards.
- adhere to specific professional standards outlined in NHSBSP guidance.

4.2. The national office of the Cancer Screening Programmes within Public Health England must

- support health professionals in their endeavour to meet standards and deliver a high quality breast screening programme.
- make available a number of resources to support health professionals on NHSBSP websites.

Risk assessment of the screening pathway

4.3. Providers

- must have in place an internal quality assurance process that assures NHS England and the quality assurance team within PHE of their ability to manage the risks of running a screening programme.
- may use the Failures Modes and Effects Analysis (FMEA) method, which is recommended by the NHS National Patient Safety Agency's risk assessment programme. Risks should be defined in the standard NHS format (where likelihood and severity are multiplied to give a RAG score).
- must maintain a register of risks, working with NHS England and quality assurance teams within Public Health England to identify key areas of risk in the screening pathway, and ensuring that these points are reviewed in contracting and peer review processes.
- identify and agree with NHS England on a quarterly basis high-scoring risks, and plans put in place to mitigate these.

Quality assurance

4.4. The provider will:

- meet national programme standards, or have plans in place to meet them
- participate fully in national quality assurance processes and respond in a timely manner to recommendations made

- ensure that data on participation from external quality assurance programmes are available to quality assurance teams within PHE, the national office of the Cancer Screening Programmes within PHE, and NHS England
- collect and submit minimum datasets as required, to assure NHS England and the quality assurance team within PHE of the safety and quality of the services provided
- participate in the 3-yearly QA visit process and provide required data for these visits in a timely fashion
- review, categorise, and record interval cancers in a timely manner and inform the quality assurance team within Public Health England as required.

Serious untoward incidents

- 4.5. Complex screening pathways often involve multidisciplinary teams working across several NHS organisations in both primary and secondary care. Inappropriate actions within one area, or communication failures between providers, can result in serious untoward incidents.
- 4.6. A screening incident is any unintended or unexpected incident(s) that could have or did lead to harm to one or more persons who are eligible for NHS screening, or to staff working in the screening programme.
- 4.7. A screening incident can affect populations as well as individuals, and be the result of an actual or possible failure in the screening pathway or of a problem at the interface between screening and the next stage of care.
- 4.8. Although the level of risk to an individual in an incident may be low, because of the large numbers of people offered screening, this may equate to a high corporate risk. It is important to ensure that there is a proportionate response based on an accurate investigation and assessment of the risk of harm.
- 4.9. Potential serious incidents or serious near misses in screening programmes should be investigated with the same level of priority as actual serious incidents.
- 4.10. Whether a “serious incident” should be declared is a matter of professional judgement on a case by case basis. It should be a joint decision by the key stakeholders informed by protocol and advice from experts and quality assurance teams.
- 4.11. In distinguishing between a screening incident and a serious screening incident, consideration should be given to whether individuals, the public or staff would suffer avoidable severe (i.e. permanent) harm or death if the problem is unresolved.

4.12. The provider will:

- comply with screening incident handling guidance developed by the national office of the Cancer Screening Programmes/ UK National Screening Committee including joint guidance developed with the UK National Screening Committee
- provide all reasonable assistance to NHS England and the cancer screening quality assurance team within Public Health England in investigating and handling an incident
- regularly review their processes and procedures against NHSBSP programme standards to reduce the likelihood of incidents occurring

Continual service improvement

The provider will

- in the event that national recommendations and core and/or developmental standards are not currently fully implemented, use service plans to indicate the changes and improvements that will be made over the course of the contract period
- develop a CSIP (Continual Service Improvement Plan) on the basis of the findings of the KPIs and the results of internal and external quality assurance checks. The CSIP will respond to any performance issues highlighted by NHS England, paying due regard to concerns raised via service user feedback. The CSIP will contain action plans with defined timescales and responsibilities, and will be agreed with NHS England

5. Costs

- 5.1. The age expansion randomisation trial will be funded directly from PHE for the length of the trial. Amounts will be calculated according to the Age Expansion Implementation Guide.

6. Teaching and research activities

- 6.1. Screening programmes will participate in the age expansion trial unless they are deemed unsuitable by the national cancer screening office in PHE. In the latter case, they have been advised to implement screening of women aged 47-49 for as long as the trial continues.
- 6.2. Any research activities undertaken by the provider must have the appropriate approvals and the national office should be informed.

Appendix 1: Current National Minimum Standards for the NHSBSP¹

Objective	Criteria	Minimum standard	Achievable standard
1. To maximise the number of eligible women who attend for screening	The percentage of eligible women who attend for screening	≥70% of invited women to attend for screening	80%
2. To maximise the number of cancers detected	a) The rate of invasive cancers detected in eligible women invited and screened	Prevalent screen ≥3.6 per 1,000 <i>Incident screen ≥4.1 per 1,000</i>	Prevalent screen ≥5.1 per 1,000 <i>Incident screen ≥5.7 per 1,000</i>
	b) The rate of cancers detected that are <i>in situ</i> carcinoma ²	Prevalent screen ≥0.5 per 1,000 <i>Incident screen ≥0.6 per 1,000</i>	
	c) Standardised detection ratio (SDR)	≥ 1.0	≥1.4

¹ Taken from current published NHSBSP guidance documents

² *In situ* carcinomas include ductal carcinoma *in situ* (DCIS), lobular carcinoma *in situ*, and microinvasive disease

Objective	Criteria	Minimum standard	Achievable standard
3. To maximise the number of small invasive cancers detected	The rate of invasive cancers less than 15 mm in diameter detected in eligible women invited and screened	Prevalent screen ≥ 2.0 per 1,000 <i>Incident screen ≥ 2.3 per 1,000</i>	Prevalent screen ≥ 2.8 per 1,000 <i>Incident screen ≥ 3.1 per 1,000</i>
4. To ensure optimal image quality for cancer detection ³	Diameter of detail (mm) 2.0 1.0 0.5 0.25 0.10	Threshold gold thickness (μm) 0.069 0.091 0.150 0.352 1.68	Threshold gold thickness (μm) 0.038 0.056 0.103 0.244 1.10
5. To limit radiation dose	Mean glandular dose per exposure for a standard breast at clinical settings	≤ 2.5 mGy	
6. To minimise the number of women undergoing repeat examinations	The number of repeat examinations	$< 3\%$ of total examinations	$< 2\%$ of total examinations
7. To minimise the number of women screened who are referred for further tests ⁴	a) The percentage of women who are referred for assessment b) The percentage of women screened who are placed on	Prevalent screen $< 10\%$ Incident screen $< 7\%$ $< 0.25\%$	Prevalent screen $< 7\%$ Incident screen $< 5\%$ $\leq 0.12\%$

³ Detail visibility should be determined using the CDMAM test object following the guidance in the latest version of NHSBSP Equipment Report 0604. Lower thresholds indicate better image quality (NHSBSP Equipment Report 0604 Rev3 "COMMISSIONING AND ROUTINE TESTING OF FULL FIELD DIGITAL MAMMOGRAPHY SYSTEMS").

⁴ Further tests include all second appointments, where procedures (including further views and/or clinical examination) beyond those normally undertaken at first appointment are carried out

Objective	Criteria	Minimum standard	Achievable standard
	short term recall		
8. To ensure that the majority of cancers, both palpable and impalpable, receive a non-operative tissue diagnosis of cancer	(a) The percentage of women who have a non-operative diagnosis of cancer by cytology or needle histology after a maximum of two visits (b) The percentage of women who have a non-operative diagnosis of DCIS by cytology or needle histology after a maximum of two attempts	$\geq 90\%$ $\geq 85\%$	$\geq 95\%$ $\geq 90\%$
9. To minimise the number of unnecessary operative procedures	The rate of benign biopsies	Prevalent screen <1.5 per 1,000 Incident screen <1.0 per 1,000	Prevalent screen <1.0 per 1,000 Incident screen <0.75 per 1,000
10. To minimise the number of cancers presenting between screening episodes in the women screened	The rate of cancers presenting in screened women a) in the two years following a normal screening episode b) in the third year following a normal screening episode	Expected standard 1.2 per 1,000 women screened in the first two years 1.4 per 1,000 women screened in the third year	
11. To ensure that women are recalled for screening at appropriate intervals	The percentage of eligible women whose first offered appointment is within 36 months of their previous screen	$\geq 90\%$	100%

12. To minimise anxiety for women who are awaiting the results of screening	The percentage of women who are sent their result within two weeks	≥90%	100%
13. To minimise the interval from the screening mammogram to assessment	The percentage of women who attend an assessment centre within three weeks of attendance for the screening mammogram	≥90%	100%
14. To minimise diagnostic delay for women who are diagnosed non-operatively	Proportion of women for whom the time interval between non-operative biopsy and result is one week or less	≥90%	100%
15. To minimise the delay for women who require surgical assessment	Proportion of women for whom the time interval between the decision to refer to a surgeon and surgical assessment is one week or less	≥90%	100%
16. To minimise the delay between referral for investigation and first breast cancer treatment	The percentage of women who are admitted for treatment within two months of the date of referral ⁵	≥90%	100%

⁵ Date of referral is the date of last read on the NBSS computer system

<u>Objective</u>	<u>Criteria</u>	<u>Minimum standard</u>	<u>Achievable standard</u>
These are the aims of the NHSBSP in relation to specific quality issues	These are the parameters by which the achievement (or non-achievement) of the objective will be measured	These figures represent the levels of performance that are the minimum acceptable for any breast screening unit. Where the minimum standard is shown as 'greater than' or 'equal to', any level of performance below that standard should be investigated by the cancer screening quality assurance team within Public Health England. Similarly, where the minimum standard is shown as 'less than' or 'equal to', any level of performance above that standard should be investigated by the quality assurance team within Public Health England.	If the programme is to achieve a reduction in mortality similar to that in the Swedish two county trial, over 50% of UK units have to achieve these standards for invasive cancer detection rate (objective 1); attendance (objective 6); and round length (objective 7). All units should aim to achieve these three key standards, which define the quantity of the mortality reduction. The other achievable standards relate to the quality of the screening process and should be achievable individually by one-third of units within the NHSBSP.

Standards shown in *italics* apply only to programmes where all women have been fully screened, i.e. women who have been invited for screening from the age of 50 up to and including the age of 70.

See *Quality Assurance Guidelines for Breast Cancer Screening Radiology*. NHS Cancer Screening Programmes, 2011 (NHSBSP Publication No 59), which includes (and, in some instances, updates) standards contained in *Consolidated Guidance on Standards for the NHS Breast Screening Programme*. NHS Cancer Screening Programmes, 2005 (NHSBSP Publication No 60).

Appendix 2: High risk surveillance protocols⁶

Ref	Risk	Ages	Surveillance Protocol	Frequency	Notes
1	a) <i>BRCA1</i> or b) <i>BRCA2</i> carrier or c) Not tested, equivalent high risk	20-29	n/a	n/a	Review MRI annually on basis of background density
		30-39	MRI	Annual	
		40-49	MRI + Mammography	Annual	
		50+	Mammography \pm MRI	Annual	
2	TP53 (Li-Fraumeni)	20-29	MRI	Annual	Review MRI annually on basis of background density
		30-39	MRI	Annual	
		40-49	MRI + Mammography	Annual	
		50+	Mammography \pm MRI	Annual	
3a	A-T homozygotes	25+	MRI	Annual	No mammography
3b	A-T heterozygotes	40-49	Mammography	18 monthly	Routine screening from 50
		50+	Mammography	Routine screening (3 yearly)	

⁶ See NHSBSP publication 74

4	Supradiaphragmatic radiotherapy-irradiated below age 30.	30-39	MRI	Annual	Surveillance commences at 30, or 8 years after first irradiation, whichever is the later. Review MRI annually on basis of background density.
		40-49	MRI \pm Mammography	Annual	
		50+	Mammography \pm MRI	Annual	

Policy for short term recalls:

5a	Repeat MRI < 6 weeks		If recall is within 6 weeks of the original assessment then it should be part of the same episode		
5b	Repeat MRI > 6 weeks		If recall is after 6 weeks then should be logged as a short term recall episode. If recall then usually it would be at 6 months.		

NOTES:

All mammography must be direct digital mammography to optimise dose and sensitivity.

All MRI must be carried out in accordance with *Technical Guidelines for Magnetic Resonance Imaging for the Surveillance of Women at High Risk of Developing Breast Cancer* (NHSBSP Publication No 68). Sheffield: NHS Cancer Screening Programmes, January 2012.

Background density assessment for continuation of MRI should be based on individual clinical judgement.

Where a woman cannot tolerate MRI, she and her lead radiologist should discuss and agree potential alternatives (e.g. wide scanners).

Screening should be suspended during pregnancy until about 6 weeks after cessation of lactation, due to the fact that the high density of the lactating breast inhibits interpretation of the image.

Ultrasound should not be used as a routine screening or surveillance technique.

For waiting time purposes, the 62 day wait period begins with the decision to recall for assessment. Where two screening examinations take place (mammography and MRI) the clock starts when the second examination is reported, provided that no other investigation has been deemed necessary after the initial mammography. If an abnormality is seen on the first examination then this should be investigated immediately, and the 62 day wait begins straight away.

Supradiaphragmatic radiotherapy means any treatment in the area of the thorax.

Untested but equivalent high risk would be as defined by a Geneticist.

Appendix 3: Routine data requirements

The Screening Programme Manager will provide NHS England with the following information:

Annually

- Results of a local client satisfaction survey
- List of completed Medical Physics surveys
- Screening services to provide tables summarising the number of eligible women in each year of the 3 year screening round and details of the 3 year screening programme including the location and timing of mobile screening
- Annual report (including a report against measures in Appendix 1)
- Number of interval cancers reviewed and categorised

Quarterly (to monitor against standards in Appendix 1, source: KC62 data)

- Number of women invited and screened (% uptake)
- Number referred for assessment (% referral)
- Number of women on short term recall (% short term recall)
- Waiting times (source NBSS reports)
 - Screen to normal result
 - Screen to actual assessment
 - Screening round length
- Technical recall/repeat rates (%)
- Summary of complaints
- Number and proportion of clinics cancelled
- Details of any untoward incidents

Appendix 4: NHSBSP guidance not otherwise referenced

Quality Assurance Guidelines for Pathologists. NHSBSP Publications No 2, July 2011 (3rd edition)

Quality Assurance Guidelines for Surgeons in Breast Cancer Screening. NHSBSP Publication No 20, March 2009 (4th edition)

Guidelines for Clinical Nurse Specialists in Breast Cancer Screening. NHSBSP Publication No 29, 2012, 5th edition

Quality Assurance Guidelines for Radiographers. NHSBSP Publications No 30, March 2000:

Quality Assurance Guidelines for Medical Physics Services. NHSBSP Publication No 33, June 2005 (2nd edition)

Quality Assurance Guidelines for Administrative and Clerical Staff. NHSBSP Publication No 47, January 2012 (*forthcoming*)

Clinical Guidelines for Breast Cancer Screening Assessment. NHSBSP Publication No 49, June 2010, 3rd edition.

Information and Advice for Health Professionals in Breast Screening. NHSBSP Publication No 53, December 2002 (*revision forthcoming*)

The Right Results – Guide to the Correct Processing and Issuing of Results. NHSBSP Publication No 55, May 2003, (*revision forthcoming*)

External Quality Assessment Scheme for Breast Screening Histopathology. NHSBSP Publication No 57, October 2003.

Guidelines for Pathology Reporting of Breast Disease. NHSBSP Publication No 58, January 2005. (*revision forthcoming*)

Quality Assurance Guidelines for Breast Cancer Screening Radiography. NHSBSP Publication No 59, March 2011 (2nd edition)

Screening for Breast Cancer in England: Past and Future. NHSBSP Publication No 61, February 2006.

Quality Assurance Guidelines for Mammography including Radiographic Quality Control. NHSBSP Publication No 63, April 2006:

Improving the Quality of the Written Information sent to Women about Breast Screening: Evidence-Based Criteria for the Content of Letters and Leaflets. NHSBSP Publication No 64, August 2007

Improving the Quality of the Written Information sent to Women about Breast Screening: Guidelines on the Content of Letters and Leaflets. NHSBSP Publication No 65, August 2007.

Uncertainties in the Management of Screen-detected Ductal Carcinoma In Situ. NHSBSP Publication No 66, July 2008

Technical Guidelines for Magnetic Resonance Imaging for Surveillance of Women at Higher Risk of Developing Breast Cancer. NHSBSP Publication 68, January 2012. (revision forthcoming)

Guidance Notes for the Acquisition and Testing of Ultrasound Scanners for use in the NHS Breast Screening Programme. NHSBSP Publication No 70, April 2011.

Commissioning and Routine Testing of Mammographic X-ray Systems – Institute of Physics and Engineering in Medicine. IPEM Report No 89 2005.

Commissioning and Routine Testing of FFD Mammography Systems or Commissioning and Routine Testing of Full Field Digital Mammography Systems. NHSBSP Equipment Report 0604, September 06, Version 2, (revision forthcoming)

Age Extension Implementation Guide. NHSBSP Publications (internal document), April 2010

Out of Area Screening. NHSBSP Publications (internal document), January 2012

Protocols for the Surveillance of Women at Higher Risk of Developing breast cancer, NHSBSP Publication 74; December 2012

Guidelines on *organising* the surveillance of women at higher risk of developing breast cancer in an NHS Breast Screening Programme. NHSBSP Publication 73, March 2013

References

ⁱ *Breast Cancer Screening Report to Health Ministers of England, Scotland, N Ireland and Wales* ed Sir Patrick Forrest DH 1986

ii *Guidelines for Managing Incidents in the NHSBSP*, pub. 44, January 2009

iii *Organising a breast screening programme* NHSBSP Publication No. 52: December 2002

iv *Guidelines for Managing Incidents in the Breast Screening Programme*. NHSBSP Publication No 44, January 2009

v *Guidelines on Quality Assurance Visits*. NHSBSP Publication No 40, October 2000, (2nd edition)

vi Professor Mike Richards, National Cancer Director Dear Colleague letter to health and social care professionals on Cancer Waits **Gateway reference:** 10900 2 December 2008