NHS
Cancer Screening Programmes

Guidance for the implementation of the Ionising Radiation (Medical Exposure) Regulations (2000, 2006)

NHSBSP Publication no 75

August 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.

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Published: August 2014
PHE publications gateway number: 2014286

Document Information

Title	Guidance notes for the implementation of the Ionising Radiation (Medical Exposure) Regulations
Policy/document type	Numbered series
Electronic publication date	August 2014
Version	1
Superseded publications	None
Review date	None
Author/s	V Jones J M Oduko E Pitcher S Sellars Z Vegnuti
Owner	NHSBSP
Document objective (clinical/healthcare/social questions covered)	Replacement of an earlier version following update of the regulations on radiation protection
Population affected	Women eligible for routine and higher-risk breast screening
Target audience	Physicists, radiographers, radiologists
Archived	Current Document

Contents

Acknowledgements

The NHSBSP is grateful for valuable input from Kathlyn Slack (Group Leader, Medical and Environmental Effects Group, Medical Exposure Department, Public Health England).

Executive summary

This document provides guidance to the NHS Breast Screening Programme on implementing the Ionising Radiation (Medical Exposure) Regulations 2000 (IRMER 2000) and subsequent amendments in IRMER 2006.[1,2] IRMER 2011[3] is concerned with medical exposures of asymptomatic individuals but explicitly excludes exposures taken as part of a national screening programme and therefore is not relevant to the NHS Breast Screening Programme.

1. Introduction

This guidance is intended for the Breast Screening Programme in England but many of its provisions will also be applicable to Scotland, Wales and Northern Ireland.

The Regulations are intended to:

- protect individuals from unintended, excessive or incorrect exposure to radiation in relation to medical exposure
- ensure that, in each case, the expected clinical benefit is assessed against the potential risk from exposure
- ensure that individuals receive no greater radiation dose than is necessary to achieve the desired benefit within the limits of current technology
- protect volunteers in medical or biomedical, diagnostic, or therapeutic research programmes and those undergoing medico-legal exposures

This document focuses in particular on the administrative and management arrangements necessary to ensure compliance with the Regulations. It should be pointed out, however, that as with all Regulations, the ultimate arbiter of their interpretation is the Court.

Although IRMER applies to all medical exposures, this guidance relates only to mammographic exposures for screening and assessment taken by NHS Breast Screening Programmes. The assessment procedures include any additional views taken on recalled women as well as magnification views and stereotactic procedures. For convenience, much of the guidance may be adapted to include procedures for any symptomatic exposures that may be conducted at NHSBSP screening units.

Any other associated matters, especially the practical measures needed to implement IRMER within NHS Breast Screening units, must be considered in conjunction with the local organisation’s radiation protection arrangements.

2. Summary of the regulations

The major requirements in IRMER that are relevant to breast screening are summarised below. Reference should be made to the wording of the actual regulations for the definitive text.

2.1 Duty holders

The regulations specify four types of duty holder: the employer, referrer, practitioner, and operator.

2.1.1 Duties of employers

The employer has a duty to ensure that written procedures for medical exposures are in place and must take steps to ensure that these are complied with by their staff (e.g. practitioners and operators.) For the NHSBSP, the employer is either the NHS Trust in which the screening unit is based or the contracted provider of the service. For the purposes of IRMER regulations, the Trust or contracted provider will still be the employer in terms of IRMER even if it contracts a third party to provide services (including the provision of operators). However, in these situations, the third party would be the employer of the operators, for employment law purposes. Equipment ownership has no impact on employer responsibilities under IRMER.

Schedule 1 of the Regulations specifies a minimum set of such procedures covering the following topics:

- patient identification
- identification of referrers, practitioners and operators
- pregnancy enquiries
- quality assurance programme for standard operating procedures
- assessment of patient dose
- diagnostic reference levels
- research procedures
- medical exposure evaluation (examination report)
- accidental or unintended exposures

The following procedures are also listed in schedule 1 of IRMER but are not generally relevant to the NHSBSP:

- medico-legal exposures
- information for patients receiving radioactive products

In addition, the employer needs to establish the following:

- recommendations concerning referral criteria, ensuring that these are made available to those acting as the referrer
- a method for authorising each exposure which ensures that there is a record that justification has taken place
- written protocols for every standard radiological practice
- up-to date records of training for practitioners and operators

Detailed guidance on developing the relevant procedures is included in the next section.

2.1.2 Duties of referrer

The referrer must be a state-registered healthcare professional who has been entitled by the employer. The referrer is responsible for supplying sufficient medical data to enable the practitioner to justify the medical exposure.

2.1.3 Duties of practitioner

The practitioner must be a state-registered healthcare professional who has been entitled by the employer. It is the practitioner's role to justify the medical exposure. The practitioner, together with the operator, is also responsible for ensuring that doses are as low as reasonably practicable whilst maintaining acceptable image quality.

2.1.4 Duties of operators

Each operator is responsible for the practical aspects they carry out in relation to a medical exposure. This includes ensuring that doses are as low as reasonably practicable whilst maintaining acceptable image quality.

Operators carry out specified practical aspects including making the exposure. This includes, for example, adjustments of the X-ray set instigated by medical physics staff, quality control by radiographic staff and those who undertake clinical evaluation. The medical physics expert (MPE) may also undertake the role of operator under IRMER.

The work of third party service engineers is not normally regarded as an operator function.

2.2 Justification

All medical exposures must be justified prior to exposure. The practitioner justifies a medical exposure in terms of the potential diagnostic net benefit, taking into account any individual detriment the exposure may cause. Operators may authorise an exposure on behalf of the practitioner by following guidelines issued by the practitioner.

2.3 Optimisation

Both practitioners and operators have a responsibility to ensure that the doses arising from exposures are kept as low as reasonably practicable consistent with the intended purpose. The following aspects are important:

- practical aspects of the exposure
- quality assurance[4,5,6]
- assessment of dose[7,8,9]
- adherence to diagnostic reference levels (DRLs)[10*]

2.4 Clinical audit

The employer must have procedures to provide for the carrying out of clinical audits.

2.5 Equipment

The employer must draw up, and keep up to date, an equipment inventory at each radiological installation.

An inventory of all equipment which either delivers or directly controls the amount of radiation must be kept by each employer. The information kept should include the manufacturer, model, serial number, year of manufacture, and year of installation. The data required is similar to that sent to the NHSBSP every six months in order to maintain the national equipment database.

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*One of the key issues in the regulations that govern the use of ionising radiation in medicine is the establishment and use of “diagnostic reference levels”. IRMER 2000 requires employers to establish DRLs and to undertake appropriate reviews if these are consistently exceeded.

2.6 Training

Under regulation 11 and schedule 2 of IRMER 2000, it is a requirement that practitioners and operators are adequately trained and undertake continuing education and training. The employer must maintain accurate and up-to-date records of the training and have them available for inspection.

3. Employer's procedures

IRMER places a duty on the employer to prepare and ensure compliance with a number of written procedures. A minimum list of such procedures is specified in schedule 1 of the regulations and is summarised in section 2.1 of this document. These employer procedures are binding and must be followed explicitly by the IRMER practitioners and operators. Each of the required written procedures is discussed in the following sections.

NHSBSP screening units may be part of a large Trust with many departments undertaking medical exposures. In this case, there may be a set of overall Trust-wide IRMER procedures covering all users. However, in many cases, a dedicated set of NHSBSP IRMER procedures may be more appropriate. The following guidance is focused on the needs of breast screening units. Local discussions will be necessary to determine whether these procedures are included in Trust-wide documents.

3.1 Patient identification

The identity of any woman attending for breast screening should be checked against the clinic list and worklist. Although a woman may be identified at more than one stage in the process, the responsibility for a final check on her identity prior to an exposure taking place lies with the operator responsible for making the exposure (the radiographer or assistant practitioner (AP)).

The final identification procedure should be positive. At least **three** confirming questions should be asked, including:

- her full name
- her date of birth and
- the first line of her address

A record must be made that the woman has been correctly identified. The employer should specify how this is to be done to ensure consistency.

Where the woman is unable to respond personally, then the final check of identity should be made with the accompanying person(s). If the woman cannot understand English and there is any possibility of incorrect identification, then assistance with interpretation must be called for. It is unlikely that the procedure required for NHS breast screening units will be significantly different from that used in other parts of the host Trust.

3.2 Referrers, practitioners, and operators

This section identifies who is entitled to act as referrer, practitioner or operator. There need to be specific procedures for these duty holders working in the NHSBSP. However, these should be written to comply with local arrangements and will vary from centre to centre.

3.2.1 Referrers

3.2.1.1 Screening procedures

Referrers are registered healthcare professionals who are entitled, in accordance with the employer's procedures, to refer individuals for mammography. Women are invited, that is, referred, for screening if they are within the eligible age range specified by the NHS Breast Screening Programme. Invitation letters are signed by the director of screening or by the lead radiologist where the director is not a registered healthcare professional. There does not need to be a signed request for each woman screened. Referral criteria for screening for higher risk groups are covered in section 4.

When a woman attends for screening, a check must be made that she meets the requirements of the NHSBSP and the breast screening unit. These requirements will include criteria such as age range and previous screening history and will be stated in local procedures. For women attending a mobile unit, the procedures should cover circumstances in which the screening would not go ahead, such as whether the woman has breast implants[†] or a physical disability which might make it more appropriate for her to attend a static screening unit. A record that each woman meets the local criteria must be kept. This may be done by initialling the clinic form or by inserting an electronic signature on the client record. Local procedures should be agreed to cover this activity.

Where a woman attends for breast screening without an invitation letter, then a radiographer may act as referrer if the referral criteria specified in the local procedures discussed above are met. (See also section 4.2). The radiographer should record that the local criteria are met. In these cases, APs **must not** act as referrers as they are not registered healthcare professionals. However, they may act as operators. It may be helpful to have local procedures which cover either mobile or static screening.

3.2.1.2 Assessment procedures

Where a woman has been recalled for further assessment following mammography screening[11, 12] the person who has reported the screening mammogram is the referrer. As all screening mammograms are double read, this may be the second reader or another person if

[†] Some digital services will perform mammography screening on women with implants on mobiles as the images can be checked immediately. This would be covered in local procedures.

arbitration by a third reader is used. As described in 3.2.2.2, the referrer may also be the IRMER practitioner for the assessment exposures.

3.2.1.3 Symptomatic procedures

If the unit also provides a symptomatic mammography service, the referrers will be healthcare professionals as defined in the Trust's general IRMER procedures.

3.2.1.4 Higher risk screening

The *Cancer Reform Strategy* (2008)[13] and *Improving Outcomes: A Strategy for Cancer* (2011)[14] stated that the breast screening programme is expected to manage higher risk breast screening for younger women. Guidance on the women to be included in the NHSBSP was first published in October 2011 and updated in April 2013 following publication of the NICE guidance.[15, 16]

3.2.2 Practitioners

It is the IRMER practitioner's function to justify exposures and he/she must have been adequately trained and have appropriate experience for this task. The following groups of professional staff may meet this requirement:

- radiologists
- breast clinicians
- breast screening radiographers

3.2.2.1 Screening exposures

Radiographers with adequate training and experience may act as IRMER practitioners and justify and authorise an exposure in their own right. Alternatively, they may act as operators to authorise an exposure by following written guidelines issued by the IRMER practitioner. In either case, the local IRMER procedures should specify who acts as the practitioner and should include specific guidelines based on the local referral criteria discussed in section 3.2.1. APs may act as operators but not as IRMER practitioners.

There needs to be a record confirming:

- that each mammographic examination has been justified
- that each mammographic examination has been authorised
- who has justified and authorised the exposure

This may be recorded by signing or initialling the client form or request form. An electronic record indicating who gave authorisation is acceptable**.**

3.2.2.2 Assessment exposures

For women recalled for further assessment, the IRMER practitioner will be the lead clinician[‡] in the assessment clinic. Imaging requirements at the time of the assessment will be decided on a case-by-case basis by the lead clinician. Some views may already have been specified by the person reporting the screening mammogram. In these cases, the referrer will also be the IRMER practitioner and, as such, should authorise the exposures and record this authorisation.

Some breast screening units may have written protocols for standard views at assessment for specific abnormalities. All units must have clear local procedures for assessment.

3.2.3 Operators

Operators are staff who undertake any practical task relating to a medical exposure. They must be appropriately trained for the tasks they undertake. They have the responsibility for ensuring that practical aspects of the exposure under their control are carried out in accordance with their professional or other relevant training and are also in accordance with the Trust's operating protocols.

There is a requirement for the employer to involve a MPE. The issues on which they should be consulted are optimisation, patient dosimetry, quality assurance, and radiation protection of the patient. The MPE can also act as an operator.

A variety of tasks and categories of operators are identified below. Trainees may fulfil any of the operations listed below provided they work under the supervision of an appropriate operator.

3.2.3.1 Selecting exposure parameters, positioning the woman, and undertaking the exposure

This can be done by:

- radiographers who possess a certificate of competence or postgraduate certificate in mammography conforming to the syllabus prescribed by the College of Radiographers
- APs who have been trained through an approved pathway which has been accredited by the College of Radiographers

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[‡] The lead clinician will be the healthcare professional leading the assessment clinic, and may be a radiologist, breast clinician or consultant radiographer.

3.2.3.2 Processing clinical films or storing and saving images to PACS

This can be done by:

- radiographers and/or other adequately trained and competent APs and helpers
- PACS managers who have relevant knowledge and experience

3.2.3.3 Reading and reporting mammograms

This can be done by:

- Radiologists and breast clinicians who have undergone specific training in reading screening mammograms
- Radiographers who have undergone specific training in reading screening mammograms

3.2.3.4 Testing of mammographic X-ray systems

This can be done by:

- medical physics staff involved in the commissioning or testing of mammographic equipment
- radiographers, APs or radiographic helpers carrying out routine quality control (QC)

3.3 Optimisation

The purpose of optimisation is to ensure that doses are kept as low as practicable, consistent with achieving the desired clinical results. This is particularly important in the context of screening. Most modern mammographic equipment is set up to provide automatic selection of the settings on the X-ray set (including tube kV_p, target and filter material) for each individual woman.

Each mammographic X-ray system should be optimised, i.e. the set-up should balance the need for adequate image quality against the need to deliver as a radiation dose which is as low as practicable. Optimisation will be based on advice from the manufacturer and also from national and local MPEs. It involves periodically reviewing and adjusting the automatic selection settings as required.

Normally, the automatic choice of settings on the X-ray set (including tube kV_p, target and filter material) should be used. However for some specific women, for example, women with breast implants, it may be necessary to use manual exposure factors or to adjust the automatic choice based on the professional judgement of the operator.

The written protocol for each radiological procedure should take into account the need for optimisation and should specify the appropriate equipment settings.

3.3.1 Protocols for mammographic exposures

Protocols for standard mammographic procedures must be written down and should reflect the need for optimisation. Screening and assessment procedures should reflect national policy. If a screening unit takes extra views for individual women, for example women with breast implants, the relevant circumstances must be documented.

The procedures for carrying out repeat mammographic procedures should be clearly laid down. The relevant circumstances must be specified and always applied.

A dated written or electronic record of the automatic exposure control (AEC) set up and the software version must be kept up to date. Exposure charts should be kept for those exposures where the AEC is not used, for example mammography of women with breast implants.

3.4 Pregnancy and breastfeeding enquiries

There is no significant radiation dose to the foetus from mammography and, from a radiation protection point of view, there is no requirement to enquire about pregnancy before imaging. However, there may be radiologically significant changes to breast tissue during pregnancy and also when breast feeding, so it may be of benefit to enquire. The NHSBSP guidance is that women should have ceased breast feeding for at least three months before mammography screening is performed.[15]

3.5 Quality assurance programme

In addition to the extensive existing quality assurance (QA) systems within the NHSBSP, there is a need under IRMER for quality assurance of these procedures.

If the employer's procedures are part of a Trust-wide document, then the IRMER procedures may be regularly reviewed by the Trust to ascertain whether they are effective and appropriate. The review should include a check on whether departmental procedures and practices are in compliance with Trust procedures and whether any changes are required. In some cases, this review may be made by the Radiation Protection Committee (RPC). A report is then made to the employer via the minutes and recommendations of the RPC.

If the breast screening unit has separate employer's procedures, then these may be reviewed by the QA team rather than the Trust RPC. A report to the employer, usually via the minutes and recommendations of the RPC, is still required.

This report, or the IRMER procedures themselves, will also be examined during the regular audit of the breast screening unit.

3.6 Assessment of patient dose

The employer needs to ensure that a record is kept of the type of investigation and other factors relevant to patient dose in order that an estimation of the breast dose to the woman can be made if necessary at a later date.

For mammography, the general level of doses given are established through regular monitoring (e.g. at least once in every screening round, or when there are changes to the mammographic equipment) of a random sample of women attending for routine screening. Thereafter, the delivery of a consistent radiation dose is checked daily using Perspex blocks.

In order to estimate the mean glandular dose to an individual woman, the projection(s), and number of exposures should be recorded. This record should include any repeat or additional images. This information can be recorded on the National Breast Screening System (NBSS).

Where appropriate, estimation of dose for an individual woman can be made by reference to the information recorded on the computerised radiology administration system (RIS), the NBSS, or the relevant paper record or mammographic image.

3.7 Diagnostic reference levels

Guidance on the establishment and use of diagnostic reference levels (DRLs) for diagnostic medical examinations is given in Department of Health guidance.[9] For mammography, the DRL is 3.5mGy per image for 55mm (50-60mm) breasts in the dose survey.

Local DRLs should be available and should be developed in conjunction with the local MPE.

The mean glandular dose to the standard breast is measured every six months on each mammography system as part of the physics quality control tests. The delivery of a consistent radiation dose is checked daily using Perspex blocks.

3.8 Research procedures

All research studies must be approved by an Ethics Committee before commencing. Dose constraints must be established for women who voluntarily undergo a mammogram as part of a clinical trial.

Research involving mammography exposures does take place within the NHSBSP. However it is unlikely that individuals will be exposed when no direct benefit is expected. Information leaflets sent to women involved in research would inform them of the benefits and harms to enable them to make an informed decision about participating in a clinical trial. In addition, participants must be informed in advance about the risks of the exposure, and must give their informed consent to their inclusion in the study. The patient information sheet must give information about the radiation dose and the potential risks in a form that is easily understandable.

3.9 Information for patients undergoing treatment or diagnosis with radioactive medicinal products

Breast screening by mammography does not involve the administration of radionuclides. However, on occasion, surgical procedures may involve sentinel node localisation using radionuclides. If these techniques are used, they will be conducted within a nuclear medicine department and their IRMER procedures will apply.

3.10 Medical exposure evaluation (examination report)

All medical exposures **must** be evaluated and the resulting diagnostic findings recorded. If the practitioner or operator knows that an evaluation will not take place then the exposure is not justified and should not be carried out.

3.10.1 Screening

All screening mammograms are double read and the final outcome will be normal or abnormal. A small number of examinations will be technical recalls. Each reader is responsible for entering their results using direct entry on NBSS.

3.10.2 Assessment

For assessment, the lead clinician will ensure that the images are evaluated and the appropriate outcome entered on NBSS.

3.11 Accidental or unintended exposures

Every employer must have standard procedures to cover accidental or unintended medical exposures of all types, including those in breast screening, and it is unlikely special procedures will need to be written for breast screening. All incidents will need to be investigated and followed up according to Trust procedures, but may also need to be reported to external bodies on the advice of the RPA.

If a woman undergoing a mammogram, is, as a result of a malfunction or defect in radiation equipment, exposed to ionising radiation to an extent much greater than intended, this should be reported to the Health and Safety Executive under regulation 32 of the Ionising Radiations Regulations (1999).[17] Guidance on what constitutes an exposure much greater than intended is given in HSE Guidance note PM77.[18] For mammography the relevant factor is ten times greater than intended.

Exposures to ionising radiation may be much greater than intended, for some reason other than a malfunction or defect in radiation equipment. In such cases, IRMER also requires that such

incidents be reported. In England, they should be reported to the Care Quality Commission. A MPE should be involved in the investigation carried out as part of the reporting requirements.

4. Referral Criteria

Women are invited for screening if they meet the referral criteria given in the Cancer Reform Strategy document. Section 3.2.1 gives further information regarding referrers and screening procedures. Each centre should have a protocol which states the current referral criteria and should have clear protocols which deal with exceptions. Guidance on some specific exceptions is given below.

4.1 Women who have been recently screened

NHSBSP has previously published guidance on justification for repeat screening in the NHSBSP.[8] However since publication in 2003, practices have been reviewed and the following guidance is now recommended:

4.1.1 If the previous mammogram was more taken more than 6 months ago, another mammogram may be justified. Wherever possible, the date of the previous mammogram should be recorded on NBSS.

4.1.2 If the previous mammogram was taken less than 6 months ago, screening should be justified on a case by case basis. The clinical director/lead radiologist should decide whether screening is justified based on all available information. The details of the individual justification must be recorded.

In both cases, it is good practice to make every attempt to obtain previous mammograms for comparison.

4.2 Women who attend for screening without an invitation

There are rare occasions when women who are eligible for breast screening attend for breast screening but do not appear on that day's clinic sheet/worklist and do not have a letter of invitation. These include:

4.2.1 Women who attend on the wrong day and have no letter

4.2.2 Women who have been previously invited but did not attend and now attend opportunistically

Mammograms must not be performed unless the woman is registered with the Breast Screening Unit. If she is registered, the mammograms may be carried out if the referral criteria are met. If she is not registered, she should be asked to contact her local breast screening service for advice.

Each unit should have clear written protocols, which enable these women to be screened. These protocols should also allow the radiographers, but not the APs, to act as referrers in certain circumstances and under certain conditions. For example, on a mobile unit, the radiographers may ring the screening office to check the woman's previous screening history, or any other appropriate detail to establish eligibility.

Women who are new to the area and have not yet been invited, but who were screened more than six months ago at a previous screening unit, should be advised to contact their local breast screening unit for information about when they will be invited.

4.3 Women over the current age range

Women over 70 remain eligible for routine breast screening once every three years.

4.4 Partial examinations

In exceptional circumstances a mammogram may be taken which would be classed as a partial examination. Appropriate information which states the limitations of the examination must be provided to women. As long as the operator can screen at least half of the breast, in any view, then the examination can be clinically justified. Reference should be made to the NHSBSP Partial Mammography Guide.[19] Local procedures should provide details about such cases.

4.5 Technical recall

In some circumstances a woman may have to be recalled for technical reasons.[20] This action will be undertaken by those staff reading images and therefore acting as referrers.

4.6 Technical repeats

Where an AP produces an inadequate image, only the radiographer acting as IRMER practitioner and the AP's supervisor (who would be a radiographer) should make the decision about repeating the image/examination.

5. Other Requirements

5.1 Training of practitioners and operators

The NHSBSP already has specific training requirements for different professionals. In most cases, it will be sufficient to refer to these standards in the employer's procedures. This professional training will ensure that topics specified in IRMER schedule 2 are covered. Employers will also be expected to ensure that relevant staff have continuing education and training in new techniques and radiation protection as appropriate.

All operators must demonstrate competency in the use of mammographic equipment.

The employer must also maintain records of training and have these available for inspection.

5.2 Clinical audit

IRMER regulation 8 requires that the employer's procedures make provision for the carrying out of clinical audit. The NHSBSP has extensive arrangements for audit already[21] and these should be referred to in the employer's procedures.

Technical recall/repeats should be audited regularly and action taken to ensure that these are kept to a minimum. The expected standard is <3% of women. Further details about this can be found in NHSBSP Publications 4 and 63.[4,21]

5.3 Expert advice

All screening units in the NHSBSP have appointed medical physics services to advise them as part of their quality assurance procedures. The employer's procedures should specify the name of the qualified MPE providing this advice, and/or refer to a written service level agreement. The agreement should specify that advice will be taken on matters including optimisation, patient dosimetry, quality assurance procedures and radiation protection of the patient. The names of the qualified MPEs should be listed in the service level agreement. They should also be listed in the local IRMER documents. These staff will also need to be given authority by the employer to act as operators with the attendant requirements.

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