

Ionising Radiation (Medical Exposure) Regulations 2017

Procedure 4: Establishing Pregnancy and Breastfeeding Status prior to an Exposure to Ionising Radiation

Required under IR(ME)R 2017 Regulation 6 & Schedule 2 (c)

CATEGORY:	Procedure
CLASSIFICATION:	Health & Safety, Clinical Governance
PURPOSE:	The procedure for making enquiries of individuals of childbearing potential to establish whether the individual is or may be pregnant or breast feeding
Controlled Document Number:	IMG004
Version Number:	2.0
Controlled Document Sponsor:	Chief Operating Officer
Controlled Document Lead:	Chair of the Radiation Safety Board
On:	5 th October 2022
Review Date:	5 th October 2025
Distribution:	
<ul style="list-style-type: none"> Essential Reading for: 	<p>Staff who are designated as an IR(ME)R operator and/or practitioner</p> <p>Staff in training to become an IR(ME)R operator</p> <p>Managers of IR(ME)R operators</p> <p>In radiotherapy, clinical oncologists acting as IR(ME)R referrer and/or practitioner</p>

Information for:	<p>Other IR(ME)R duty holders (referrers)</p> <p>General managers of departments and areas that perform procedures involving ionising radiation</p> <p>All staff working in departments that perform procedures involving ionising radiation.</p>
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1. Procedure Statement

- 1.1 To ensure that enquiries with regard to pregnancy and breastfeeding are made in an appropriate and consistent manner prior to diagnostic medical exposures to ionising radiation. The privacy and confidentiality of the individual to be exposed must be respected when applying this procedure.

2. Scope

- 2.1 All medical exposures (excluding those to comforters and carers) and non-medical imaging exposures carried out by the Trust
- 2.2 The Equality Act (2010) requires an inclusive pregnancy status check. It is therefore paramount that all patients of childbearing potential are identified, including those who do not present as “female”.
- 2.3 The Society of Radiographers has issued inclusive pregnancy status guidelines for ionising radiation ([Inclusive pregnancy status guidelines for ionising radiation: Diagnostic and therapeutic exposures | SoR](#)). These guidelines have been taken into account in the development of this procedure.
- 2.4 Pregnancy status must be ascertained for any individual¹ between the ages of 11 to 55 of childbearing potential who is to undergo:
- Radiographic examination of the pelvic area (above knee and below diaphragm), prior to exposure
 - Any diagnostic or therapeutic nuclear medicine exposure prior to the administration of the radioactive substance
 - All Radiotherapy localisation or treatment, prior to planning CT and before the first treatment fraction.
- 2.5 See section 11 for special instructions that must be applied when the individual is 11 to 15 years old (inclusive).
- 2.6 Making pregnancy or breastfeeding enquiries in advance of an exposure is an operator task; however, the referrer is responsible for providing sufficient medical data to enable the practitioner to justify the exposure. This data should include the pregnancy status of the individual.
- 2.7 Where the referrer indicates in the request that the individual has been through early menopause, had a hysterectomy, has been sterilised, has a condition preventing pregnancy or cannot become pregnant for any other reason, the operator must confirm this status prior to an exposure or set of exposures.

¹ Any reference to “individual” means “individual to be exposed to radiation”. Particular care should be taken to identify individuals who do not present as female but may be capable of pregnancy as per Society of Radiographers National Guidance

- 2.8 Breast feeding (sometimes referred to as chest feeding or body feeding) status must be ascertained for any individual of childbearing potential who are to receive an administration of a radioactive substance
- 2.9 Where clinical urgency dictates immediate imaging, e.g. in level 1 and level 2 trauma cases, the urgency of the exposure overrides the need to determine pregnancy status.

3. Responsibility

- 3.1 The operator is responsible for making pregnancy or breast feeding enquiries prior to an exposure.
- 3.2 In Radiotherapy:
- The clinical Oncologist or specialist registrar (referrer / practitioner) is responsible for checking the individual's pregnancy status at the time of consent, explaining the risks of foetal irradiation, and the need to report to staff immediately if there is a possibility, they have become pregnant at any time during treatment.
 - This must be confirmed by the operator immediately prior to CT and again prior to the first treatment exposure

4. Practice: low dose diagnostic procedures

- 4.1 Low dose procedures are those that result in a dose to the uterus of <10mGy. They include:
- Plain film x-ray examinations in which the primary beam is incident between knees and diaphragm²
 - Diagnostic nuclear medicine procedures in which the uterus dose is <10mGy, as listed in the current edition of the ARSAC Notes for Guidance at [ARSAC notes for guidance: good clinical practice in nuclear medicine - GOV.UK \(www.gov.uk\)](http://www.gov.uk/government/uploads/system/uploads/attachment_data/file/271247/arsac-notes-for-guidance-good-clinical-practice-in-nuclear-medicine-gov-uk.pdf)
- 4.2 Every individual undergoing the procedures described in 4.1 must be asked about pregnancy status, for example:
- What sex were you registered as at birth?
 - If the answer is "female or Other with a potential of pregnancy":
 - Are you or might you be pregnant?
 - If yes you are pregnant, how many weeks are you?

²X-ray examinations in which the primary beam will not irradiate the lower abdomen or pelvis can proceed without any additional precautions relating to potential pregnancy

- When was the date of the first day of your last menstrual period?
 - Is your menstrual period overdue?
 - Are you using any form of contraception?
- 4.3 If the response indicates that the individual is not pregnant, the exposure can proceed
- The operator must complete Form A and the relevant field on the Radiology Information System (RIS).
- 4.4 If there is any uncertainty about the pregnancy status, the operator should ask further questions as appropriate. If it is established that the individual is not pregnant, the exposure can proceed:
- The operator must complete Form A and the relevant field on the RIS
- 4.5 If pregnancy cannot be excluded, an appropriate practitioner must review the justification and decide whether:
- The exposure can be delayed, bearing in mind that if the individual is pregnant the delay may extend until after delivery; or
 - The benefit of the exposure outweighs the potential harm to both the individual and the foetus, and can proceed

Information from the referrer as to the immediate over-riding clinical need for the procedure should be taken into consideration, for example for the diagnosis of pulmonary embolism in pregnancy.

- 4.6 If the practitioner is satisfied that the exposure can be delayed, the individual should be asked to phone on the first day of their next period to rearrange the examination
- 4.7 If the individual is known or suspected to be pregnant and the exposure will proceed, the Practitioner must sign Form B to acknowledge that they agree to proceed
- 4.8 The decision must be recorded on the RIS, along with the justification and the name of the practitioner. The individual must be informed of the decision and potential risks and benefits

5. Practice: high dose diagnostic procedures

- 5.1 High dose diagnostic procedures are those where the foetal dose is likely to be >10mGy and include the following:
- CT scans where the primary beam is incident on the abdomen and/or pelvis.
 - Interventional procedures involving direct exposure of the abdomen and/or pelvis.

- Diagnostic nuclear medicine procedures in which the uterus dose is >10mGy, as listed in the current edition of the ARSAC Notes for Guidance at [ARSAC notes for guidance: good clinical practice in nuclear medicine - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/61422/arsac-notes-for-guidance-good-clinical-practice-in-nuclear-medicine-gov.uk). The practitioner and operator must also take into account the dose from any CT exposure undertaken as part of the examination.
- 5.2 Every individual undergoing the procedures described in 5.1 must be asked about pregnancy status, for example:
- What sex were you registered as at birth?
 - If the answer is “female or Other with a potential of pregnancy”:
 - Are you or might you be pregnant?
 - If yes you are pregnant, how many weeks are you?
 - When was the date of the first day of your last menstrual period?
 - Is your menstrual period overdue?
 - Are you using any form of contraception?
- 5.3 If the response indicates that the individual is unable to become pregnant, the exposure can proceed.
- 5.4 If the response indicates that the individual is able to become pregnant, but definitely is not, the exposure can proceed.
- The individual must sign the Form A to confirm that they are not pregnant
 - The operator must scan the form in to the RIS and complete the relevant field
- 5.5 If there is any uncertainty about the pregnancy status, the operator will ask further questions as appropriate.
- 5.6 If it is established that the individual is able to become pregnant but that the start of their last menstrual cycle was less than ten days ago, the exposure can proceed.
- The operator must make a note in the relevant field of the RIS
- 5.7 If the answers indicate that:
- The individual is able to become pregnant; *and*
 - The start of the individual’s last menstrual cycle was more than 10 days ago; *and*
 - The individual is able to state definitively that they are not pregnant
- The exposure can proceed;
- The individual must sign the Form A to confirm that they are not pregnant

- The operator must scan the form in to the RIS and complete the relevant field.

5.8 If the answers indicate that:

- The individual is able to become pregnant; and
- The start of the individual's last menstrual cycle was more than 10 days ago; and
- The individual is unable to state definitively that they are not pregnant

An appropriate practitioner must review the justification and decide whether:

- The exposure can be delayed, bearing in mind that if the individual is pregnant the delay may extend until after delivery; or
- The benefit of the exposure outweighs the potential harm to both the individual and the foetus, and can proceed

Information from the referrer as to the immediate over-riding clinical need for the procedure should be taken into consideration.

5.9 If the practitioner is satisfied that the exposure can be delayed, the individual should be asked to phone on the first day of their next period to rearrange the exposure for within the next ten days

5.10 If the individual is known or suspected to be pregnant and the exposure will proceed, the Practitioner must sign Form B to acknowledge that they agree to proceed

5.11 Any decision must be recorded on the electronic patient information system, along with the justification and the name of the practitioner. The individual must be informed of the decision and potential risks and benefits

6. Practice: Nuclear Medicine Therapy Patients

6.1 Every individual undergoing radionuclide therapy must be asked about pregnancy status, for example:

- What sex were you registered as at birth?
- If the answer is "female or Other with a potential of pregnancy":
 - Are you or might you be pregnant?
 - If yes you are pregnant, how many weeks are you?
 - When was the date of the first day of your last menstrual period?
 - Is your menstrual period overdue?
 - Are you using any form of contraception?

6.2 If the answers indicate that the individual is unable to become pregnant the exposure can proceed. The operator must complete the relevant field on the RIS

For all other individuals in the age range 11-55 years old, a urine HCG pregnancy test must be performed on the day of treatment. The therapy must only proceed if the pregnancy test is negative.

7. Practice: Radiotherapy

- 7.1 When an individual between the ages of 11 to 55 is consented for the radiotherapy treatment by a clinician, pregnancy status must be ascertained in accordance with the oncology department procedures
- 7.2 The pregnancy status must be confirmed by the operator before the planning CT exposure, and again before the first treatment fraction using the following questions
- What sex were you registered as at birth?
 - If the answer is “female”:
 - Is there any chance you could be pregnant?
 - Is your menstrual period overdue? *If yes:*
 - What is the date of your last menstrual period?
- 7.3 If the answers indicate that the individual is capable of becoming pregnant and is unable to definitively state that they are not pregnant, then a pregnancy test will be performed following standard trust procedures.
- 7.4 If the individual is able to confirm that they are not pregnant, or results of the pregnancy test are negative then the individual must be reminded of the requirement to avoid pregnancy and the exposure can continue,
- The operator must record the response in the electronic patient record system
- 7.5 If the results are positive or inconclusive the Clinical Oncologist must consider the justification and decide whether:
- The benefit of the exposure outweighs the potential harm to both the individual and the foetus, and can proceed; or
 - The exposure can be delayed, bearing in mind that if the individual is pregnant the delay may extend until after delivery
- 7.6 Any decision must be recorded in the individual’s notes, along with the justification and the name of the referrer and/or practitioner. The individual must be informed of the decision and potential risks and benefits

8. Practice: Breast feeding

- 8.1 For any Nuclear Medicine test the operator who is to administer the activity to the individual must ask the individual “Are you breastfeeding” before they administer the activity.

- 8.2 If the individual is breast feeding advice should be sought from a Medical Physics Expert about how to proceed. Information will be based upon the current ARSAC notes for guidance and other evidence, where available (for example International Commission on Radiological Protection (ICRP) guidance). Where advised, the operator should arrange for the individual to provide samples of breast milk for the measurement of activity to determine when breast feeding may be restarted.
- 8.3 Breast-feeding is contra-indicated for all therapeutic radionuclides that would be expressed in breast milk.

In addition, patients treated with some radionuclides will have to avoid close contact with children for various times after treatment to restrict external radiation dose on the advice of a medical physics expert.

Medical Physics Experts will be able to advise on the contact restrictions in such cases.

9. Practice: Individuals with specific communication needs

- 9.1 When practicable, where an interpreter is necessary, one should be used that is not a relative of the individual. Wherever possible the question of pregnancy should not be asked when a relative is present.
- 9.2 For individuals with learning disabilities, an advocate who is willing and able to confirm the pregnancy status of the individual may answer on their behalf. Alternatively, the operator must gain as much information as possible and contact the practitioner.

10. Practice: Individuals 11 to 15 years of age (inclusive)

- 10.1 Pregnancy in individuals under the age of 16 may be a safeguarding issue; advice must sought from the Trust Safeguarding team.
- 10.2 The operator will need to use professional judgement when asking about pregnancy status, in accordance with the Trust Consent to Examination or Treatment policy
- 10.3 All individuals should be asked:
- What sex were you registered as at birth?
 - If the answer is “female or Other with a potential of pregnancy”:
 - Do you have periods and are they regular?”
 - For individuals with regular periods follow the same practice as used for adults.
 - If the individual has not started having periods, record this on the electronic patient management system and proceed with the exposure.
 - If the periods are irregular the operator may use professional judgement

to ascertain pregnancy status if possible

- If pregnancy cannot be excluded apply the 10 day rule as for high dose procedures (see section 5) even if the test is actually a low dose one.

10.4 The process for Radiotherapy is shown in the flow chart in Appendix 1

11. Practice: Trauma, unconscious or anaesthetised patients

11.1 Whenever practicable it should be determined whether an individual who is unconscious or unable to respond is pregnant and the practitioner must take this into consideration when carrying out justification of the procedure.

11.2 If a patient is to have a medical exposure in theatre, pregnancy status will be established by theatre staff using the Theatre Care Plan.

11.3 The operator initiating the exposure should determine whether pregnancy status has been established. In the unlikely event that pregnancy status has not been checked and a patient is anaesthetised, the examination should continue however, the operator must complete an incident form (Datix) in line with the Trust policy.

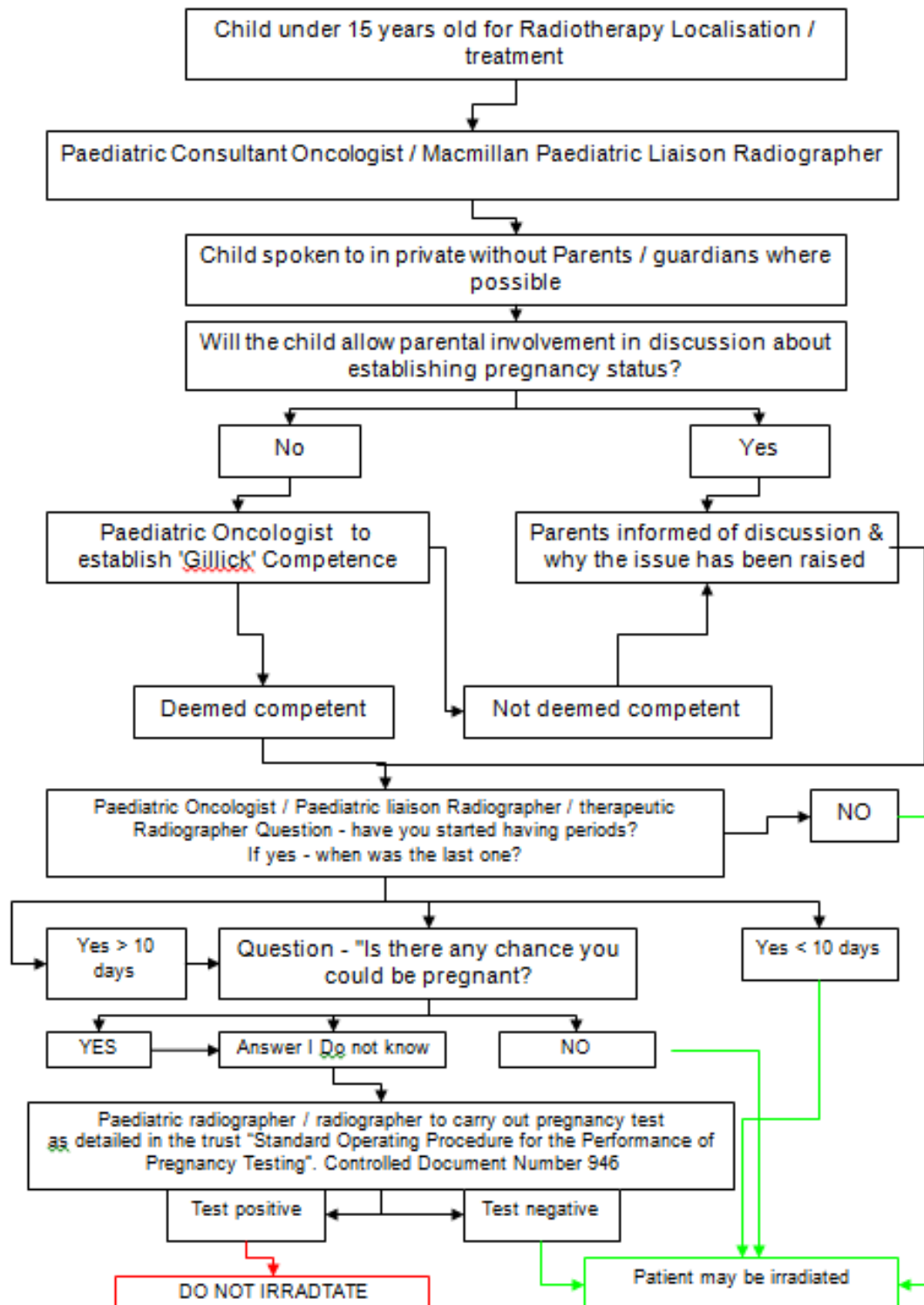
11.4 Pregnancy status must be ascertained post-surgery and if relevant the foetal dose will be assessed.

12. Contingencies

12.1 Any failure in compliance with this procedure must be reported to the relevant Divisional General Managers or Medical Physics Expert in their absence. Failure to comply with the above procedure may result in the Trust's Disciplinary Policy being invoked.

Appendix 1

Radiotherapy Procedure for checking pregnancy status of child bearing capable patients (11-15yrs)



Appendix 2

Form A: Inclusive Pregnancy form for the diagnostic and therapeutic use of radiation

Name

Date of birth

Your Doctor/Healthcare professional has requested you undergo a procedure/investigation that requires an exposure to ionising radiation. It is our professional duty and legal responsibility to determine whether someone having this type of procedure could be pregnant before deciding whether to go ahead.

Please note, we may not be able to continue today if we are unable to confirm your pregnancy status.

As you are aged between 11 and 55 years old, please answer the following questions.

1. Which sex were you assigned at birth? MALE / FEMALE / OTHER (please circle)

If you have answered **Male** please move onto patient signature below. If you have answered **other** and have a potential of pregnancy please discuss with the healthcare professional looking after you today.

Only answer the following if you have answered Female or Other with a potential of pregnancy

2. Have your menstrual periods begun? YES/NO
 3. Are you or might you be pregnant? YES / POSSIBLY / NO (please circle)
 4. If YES you are pregnant how many weeks pregnant are you?
- If NO please move onto patient signature, if POSSIBLY please continue to question 5.
5. When was the date of the first day of your last menstrual period?
 6. Is your menstrual period over due? YES / NO / UNSURE
 7. Are you using any form of contraception? YES / NO

Patient Signature

Date

Staff Signature

Date

Staff to complete

PID/NHS number:

Date

Radionuclide therapy only (staff to complete)

Pregnancy HCG test results

Batch No.

Date

Positive Negative

Staff signature

Appendix 3

Form B: Justification of patients suspected or are pregnant undergoing diagnostic radiation exposure.

IR(ME)R PRACTITIONER

I confirm that acting as an IR(ME)R practitioner I have reviewed the justification and risk alongside the clinical history and clinical question for the below requested investigation using ionising radiation on the below named patient, who may be / is pregnant. I confirm that in my opinion the test is justified/low risk and should be performed at this time.

Operator to complete

Investigation requested **Date requested**

Patient Name: **Date of birth:**

PID/NHS number:

Practitioner to complete after Authorisation

Signature of IR(ME)R Practitioner: **Date:**

.....

Print name of IR(ME)R Practitioner: **Position:**

.....

.....

In the event of remote Practitioner Authorisation the Operator must fill in the below details before exposure is performed.

IR(ME)R Practitioner Name

IR(ME)R Practitioner position

I confirm justification and authorisation has taken place by the IR(ME)R Practitioner in relation to the exposure of ionising radiation and verbal agreement to proceed has been obtained

Signature of IR(ME)R Operator

Date

Time