

## Document Control

<b>Title</b>			
<b>Radiological Examination of Individuals of Reproductive Capacity Standard Operating Procedure</b>			
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## 1. Operators who receive requests from Referrers

### Introduction

This Standard Operating Procedure sets out the duties and responsibilities under the Ionising Radiation (Medical Exposure) Regulations IR(ME)R, of Practitioners and for imaging investigations involving the use of ionising radiation on Individuals of child bearing capacity.

Irradiation of a foetus should always be avoided whenever possible and alternative imaging techniques should be considered before a decision is taken to expose Individuals of child bearing capacity to ionising radiation.

Where pregnancy is not necessarily suspected by the Individual themselves, checks must be made to ensure that there is no possibility of pregnancy before the Operator proceeds with the examination, particularly if the abdomen or pelvic area is to be irradiated.

This standard operating procedures also includes those individuals whose gender was female at birth and are transgender or non-binary.

## 2. Purpose

To:

- Avoid the unintentional exposure of a developing foetus to ionising radiation during pregnancy
- Ensure that all Individuals of child bearing capacity between the ages of 12 – 55 years are consulted about the possibility of pregnancy prior to undergoing imaging investigations using ionising radiation.

- Provide clear guidance to radiographers on the course of action to be taken by them in the event that a Individual is uncertain about their pregnancy status.

### 3. Definitions

**IR(ME)R:** (Ionising Radiation [Medical Exposure] Regulations 2017)

**CHILD BEARING AGE:**

All Individuals of childbearing capacity between the ages of 12 to 55 years.

**ABDOMEN OR PELVIC AREA:**

Any anatomical area irradiated by the primary x-ray beam from the diaphragm down to but not involving the knee joints

**10 & 28 DAY RULES:**

These rules refer to the point in the Individual's menstrual cycle when it is considered most likely that the untoward effects of radiation in pregnancy can be avoided.

When taking into account either of these rules, the act of delaying a procedure that is needed to evaluate a new symptom or diagnose a new disease is not justified if the delay could prove detrimental to the health and welfare of the patient

**LMP:**

Date of last menstrual period

**LOW DOSE PROCEDURES:**

**If pregnancy cannot be excluded the 28 day rule applies**

The low dose procedure is defined as any procedure in which the foetal dose is likely to be below 10mGy. The vast majority of routine diagnostic examinations fall into the category of a low dose procedure.

If pregnancy cannot be excluded but the menstrual period is not overdue according to the 28 day rule proceed with the examination.

The Low Dose LMP form should be completed by the operator and the patient (see Appendix 1). If the patient's menstrual period is overdue the patient should be treated as possibly pregnant and the advice on the flow chart (Appendix 2) should be followed

**HIGH DOSE PROCEDURES: where the dose to the foetus is likely to be greater than 10mGy:**

**If pregnancy cannot be excluded the 10 day rule applies**

The following examinations are considered to be high dose:

- CT examinations of the abdomen or pelvis
- All high dose fluoroscopic and interventional procedures where the primary beam directly irradiates the abdomen or pelvis

According to the **10 day rule**, Individuals of child bearing capacity must be booked for high dose examinations during the first 10 days of their menstrual cycle when conception is unlikely to have occurred.

It is the responsibility of the Operator to ensure that pregnancy checks are made prior to the procedure and the High Dose LMP form is signed by the patient.

If the patient's menstrual period is overdue the patient should be treated as possibly pregnant and the advice in section 7.1 (The Referrer) should be followed. Also see flow chart Appendix 2

## 4. Scope

This Standard Operating Procedure (SOP) relates to the following staff groups who may be involved in the discussion, assessment and notification of pregnancy status to other imaging professionals:

- Medical staff (including surgeons and GPs)
- Registered nurses
- Radiographers
- Support workers

Medical staff, registered nurses, radiographers and those trained in caring for patients undergoing diagnostic imaging procedures should assess the need for 10 or 28 day LMP checks with the patient and apply the appropriate rule. Staff must ensure the relevant information is documented on the appropriate 'high dose' or 'low dose' forms (**see Appendix 1**).

### Capacity

Patients, who have capacity to answer questions about the date of their LMP and give informed consent to undergo diagnostic imaging procedures, should complete and sign the appropriate Pregnancy Declaration form.

If the patient is unable to answer for themselves because of language difficulties, then a translator is required (this may be a relative).

If the patient is unable to answer and/or sign the Pregnancy Declaration Form themselves because they have special needs, then an accompanying guardian or primary carer can answer and/or sign on their behalf.

For unconscious patients such as trauma cases, possible pregnancy must be assumed and examinations undertaken accordingly with the referring clinician and Practitioner signing the relevant part of the Pregnancy Declaration Form.

Patients, who are pregnant and have capacity to make an informed decision and consent to undergo diagnostic imaging procedures, should complete and sign the Pregnancy Declaration form

## 5. Location

This Standard Operating Procedure will be implemented in all clinical areas including endoscopy and theatres where Operators are required to use ionising radiation to obtain diagnostic images. Operators must obtain and record the required pregnancy information and ensure that the relevant declaration form is signed BEFORE making an exposure.

Staff undertaking this procedure must be able to demonstrate continued competence as per the organisations policy on assessing and maintaining competence.

## 6. Equipment

- LMP Check forms:- (See Appendix 1)
  - High dose (A)
  - Low dose (B)
  - Pregnancy Declaration Forms
  - Pregnancy Flow Chart for LMP (See Appendix 2)

## 7. Procedure

### 7.1. RESPONSIBLE PERSONNEL

#### Duty Holders:

#### The Referrer

The referrer must be aware of the need to provide sufficient clinical information to allow the examination to be justified, and must therefore:

- Clearly indicate on the request form if it is known or suspected that the patient is pregnant at the time the request was made;
- Disclose any information that may be relevant e.g. if the patient has been sterilised, or has an intention to become pregnant;
- Indicate on the request form the date of the patients LMP
- Indicate on the request card if he/she considers that the clinical necessity of performing the examination overrides the question of possible pregnancy.
- **If the patient is definitely or possibly pregnant:** - justification for the proposed examination must be reviewed with a medical IR(ME)R practitioner (usually a Radiologist, who may wish to consult the referring clinician) and decide whether or not to defer the investigation until after delivery (or until pregnancy has been ruled out). If, after review, a procedure is still considered to be justified and is undertaken, the foetal

dose should be kept to the minimum consistent with the diagnostic purpose. A pregnancy declaration form should be completed by the operator and the patient (**see Appendix 1**).

**The Practitioner** is responsible for assessing all available information concerning possible pregnancy and must therefore:

- Ensure that the clinical information supplied on the request card is correct and sufficient to justify the examination;
- Ensure that the date of the LMP has been recorded on the request card;
- Have due regard for either the 10 or 28-day rule depending on the examination requested;

**Where a conflict or doubt exists between either of the above rules and the patient's recorded LMP, consider the need to either:**

- Rebook the patient for a later date, if appropriate
- Complete a pregnancy declaration form (see appendix1)
- Or defer the examination until after a pregnancy test has been carried out

Careful consideration should be given to cases where the referrer has advised that the question of pregnancy should be waived. If in any doubt, the advice of a Consultant Radiologist should be obtained.

**The Operator** has the final responsibility before initiating the exposure for:

- Checking with the patient any information already provided prior to proceeding with the examination
- Obtaining the signature of the patient on a pregnancy declaration form (see appendix 1) if this has been deemed necessary
- Being entirely satisfied that the question of pregnancy has been resolved in accordance with the approved protocol.
- Following the steps indicated on the flow chart (Appendix 2).

**Before completing the examination, the operator must:**

- Complete the LMP field on CRIS, either entering the date of the LMP or an appropriate comment as to why the LMP has been disregarded
- Record the DAP meter reading and/or screening time in the appropriate field on CRIS,
- If any repeat images were taken, record the reason why the original images were rejected.

**Acceptable reasons for disregarding the 10 & 28 Day Rules** – the circumstances when it can be considered acceptable to proceed with the examination are listed below:

- Overriding clinical reasons
- Hysterectomy
- Sterilisation or other form of contraception
- Signed pregnancy declaration form (**see Appendix 1**)

**Negative pregnancy tests:**

Pregnancy test results are to be used with caution, as even high sensitivity tests are unable to detect pregnancies less than 4 weeks old. Standard sensitivity tests will not usually detect a pregnancy less than 5 weeks old)

**Irregular periods:**

Some patients will not have regular periods and therefore may not fit neatly into the flowchart. If they are able to state that they are not pregnant, then the Operator may go ahead with the radiological procedure.

If the patient is unable to state with confidence that she is not pregnant, a pregnancy test may be required.

**Patients below the age of 16 years:**

If practicable, children under the age of 16 should be asked about the possibility of pregnancy without their parents being present. In any case, a child's signature (rather than a parent or guardian's) is appropriate to this situation provided that in the opinion of the health professional they understand what is being asked.

If the health professional doubts that the child understands the significance of the question they must then involve the parent/guardian who may sign the disclaimer on the child's behalf.

**In the case that a foetus is inadvertently exposed:**

- Report the incident to an RPS or radiology manager and complete a Radiation Incident form.
- The RPS will complete a radiation incident form recording all relevant data and contact the Medical Physics Expert (MPE) who will investigate the cause and the estimated dose to the foetus.
- The Radiologist or Clinician should counsel the patient on the event and the associated risk using the information provided by the MPE investigation.
- The MPE and/or the RPA will ascertain whether the incident needs to be reported to the CQC as an exposure 'much greater than intended'.

## 8. References

Ionising Radiation (Medical Exposures) Regulations 2017. Statutory Instruments 2017 No 1322

[http://www.legislation.gov.uk/ukxi/2017/1322/pdfs/ukxi\\_20171322\\_en.pdf](http://www.legislation.gov.uk/ukxi/2017/1322/pdfs/ukxi_20171322_en.pdf)

Protection of Pregnant Patients during Diagnostic Medical Exposures to Ionising Radiation, Advice from the Health Protection Agency, The Royal College of Radiologists & the College of Radiographers, 2009

## 9. Associated Documentation

Northern Devon Healthcare NHS Trust Policies for :

- Patient Identification

[\\Nds.internal\public\Radiology\\_Clinical\\_Governance\IRMER\IR\(ME\)R Procedures - Standard Operating Procedures\IR\(ME\)R Procedure 3 SOP Identification of Patients in Radiology \(V2.0 Updated\).docx](#)

- Making a Referral for Clinical Imaging (SOP)

[\\Nds.internal\public\Radiology\\_Clinical\\_Governance\IRMER\IR\(ME\)R Procedures - Standard Operating Procedures\IR\(ME\)R procedure 2 SOP Making a Referral for Diagnostic Imaging \(V1.0 Updated\).doc](#)

- Appendix 1 – Pregnancy declaration forms
- Appendix 2 – Flow chart for LMP status

## 10. Radiation in Pregnancy Statement

Patient ID Sticker

Name .....

.....

DOB .....

.....

RBZ # .....

.....

**RADIATION PREGNANCY STATEMENT A**

**HIGHER DOSE PROCEDURE: 10 DAY RULE**

**If you are pregnant, or think that you might be, it is best to avoid radiation exposure, unless your doctor decides that your test is very urgent.**

Advice from the Health Protection Agency and the Royal College of Radiologists requires us to establish whether there is any possibility of pregnancy in all individuals of childbearing capacity between the ages of 12 -55 years.

**Please sign below to indicate that you have understood the Radiation Pregnancy Statement above and that to the best of your knowledge you are not pregnant.**

**PLEASE PRINT**

I (Patient's Name) \_\_\_\_\_ state that there is no possibility of my being pregnant on this date \_\_\_\_\_ and that the **first** day of my last menstrual period was \_\_\_\_\_

Is your period overdue? **YES / NO**    Date of pregnancy test (if done) \_\_\_\_\_

If the date of your last period is unknown, please indicate a reason below:

\_\_\_\_\_

If you would like to discuss this privately with a member of clinical staff there will be an opportunity to do so before your examination.

Patient's signature \_\_\_\_\_ Date \_\_\_\_\_

Parent/Guardian/Primary Carer /Interpreter signature \_\_\_\_\_ Date \_\_\_\_\_

Staff signature \_\_\_\_\_ Designation \_\_\_\_\_

**For Radiology Department use:**

I consider that the clinical necessity for this higher dose examination is such that the above requirement may be disregarded.

Referring Clinician \_\_\_\_\_ Date \_\_\_\_\_

Radiologist/Practitioner \_\_\_\_\_ Date \_\_\_\_\_

Patient ID Sticker

Name .....

.....

DOB .....

.....

RBZ # .....

.....

**RADIATION PREGNANCY STATEMENT B**

**LOWER DOSE PROCEDURE: 28 DAY RULE**

**If you are pregnant, or think that you might be, it is best to avoid radiation exposure, unless your doctor decides that your test is very urgent.**

Advice from the Health Protection Agency and the Royal College of Radiologists requires us to establish whether there is any possibility of pregnancy in all individuals of childbearing capacity between the ages of 12 -55 years.

**Please sign below to indicate that you have understood the Radiation Pregnancy Statement and that to the best of your knowledge you are not pregnant.**

**PLEASE PRINT**

I (Patient's Name) \_\_\_\_\_ state that there is no possibility of my being pregnant on this date \_\_\_\_\_ and that the **first** day of my last menstrual period was \_\_\_\_\_

Is your period overdue? **YES / NO**    Date of pregnancy test (if done) \_\_\_\_\_

If the date of your last period is unknown, please indicate a reason below:

\_\_\_\_\_

If you would like to discuss this privately with a member of clinical staff there will be an opportunity to do so before your examination.

Patient's signature \_\_\_\_\_ Date \_\_\_\_\_

Parent/Guardian/Primary Carer /Interpreter signature \_\_\_\_\_ Date \_\_\_\_\_

Staff signature \_\_\_\_\_ Designation \_\_\_\_\_

**For Radiology Department use:**

I consider that the clinical necessity for this lower dose examination is such that the above requirement may be disregarded.

Referring Clinician \_\_\_\_\_ Date \_\_\_\_\_

Radiologist/Practitioner \_\_\_\_\_ Date \_\_\_\_\_

## Appendix 1 – Pregnancy Declaration Form

### Risks of X-Rays and CT scans in Pregnancy

#### Q. Can I have an X-Ray or CT whilst pregnant?

There is always concern about potential harm to the unborn child from X-Ray or CT scan radiation. Sometimes, due to a particular medical concern, your doctor may feel an X-ray is needed. The decision will be taken based on the balance of the risks of doing the X-ray and the benefit of the information from the X-ray.

#### Q. What are the risks?

The risk to you and your unborn child are very small and the risk of not having the X-ray could be much greater than the risk of the radiation. Birth defects, which are often believed to be the major concern, only occur with much higher dose exposure in early pregnancy i.e. the first three months. The very small risk of low dose radiation is childhood cancer.

During the course of a normal pregnancy a baby is exposed to normal low dose environmental radiation. This can be from cosmic rays reaching the earth from space, from certain rocks (which may be contained in building materials), from travel (particularly air flight), and from naturally occurring radon gas (particularly widespread in granite areas of the country such as Devon, Cornwall & Dartmoor). In any one year our exposure will vary according to where we've lived, where we may have flown to and what we may have eaten.

The first detectable risk of cancer occurs when the baby is exposed to a dose 20 times more than the environmental radiation, such as from the sun. At this level of exposure your baby has a 1 in 500 chance of developing childhood cancer.

#### Q. How many tests are safe?

The list below shows how many tests you would need to have for your baby to receive 20 times more than environmental radiation.

Type of X-ray or scan	Quantity
X-ray of your Chest	More than 50 tests
X-ray of an Upper Extremity	More than 50 tests
X-ray of a Lower Extremity	More than 50 tests
X-ray of your pelvis	Between 5 and 30 tests
X-ray of your lower spine	Between 3 and 20 tests
V/Q Lung scan	Approximately 5 or more tests
CT Scan of your head	Approximately 50 tests
CT Scan of your chest	Between 3 and 6 tests
CT Scan of your abdomen	Between 1 and 3 tests

**All X-Ray examinations are only performed if the risk of not having the information they will provide is greater than the very small risk from the radiation.**

If you have any questions or concerns, please ask your doctor.

An X-Ray or CT procedure of a pregnant patient is carried out when the patient's physician has decided that the advantages of the exposure outweigh the potential risk.

**By signing this form you are consenting to understanding the need for the test and the small potential risk explained in the Risks of X-Rays and CT scans in Pregnancy factsheet overleaf.**

**I consent to this procedure and acknowledge that I have been given the opportunity to ask all questions and have them answered to my satisfaction.**

Patient's name: \_\_\_\_\_

Hospital number: \_\_\_\_\_

**Patient's signature:** \_\_\_\_\_

---

Interpreter's name( if used): \_\_\_\_\_

Interpreter's signature (if used): \_\_\_\_\_

---

Doctor responsible for consent (name & grade): \_\_\_\_\_

Contact number: \_\_\_\_\_

**Doctor responsible for consent (signature):** \_\_\_\_\_

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Radiographers:

The Patient has been given all of the information they required to make the informed decision to consent for this procedure.

They have had the Opportunity to ask further questions if needed prior to acquisition.

Was patient contact shielding applied? Yes  No  (*If yes please justify below*)

---

Exposure Factors/DAP: \_\_\_\_\_

Radiographer undertaking the examination (name): \_\_\_\_\_

**Radiographer undertaking the examination (signature):** \_\_\_\_\_

**Date:** \_\_\_\_\_

## Appendix 2

# IR(ME)R Flow Chart for Radiological Examinations in Individuals of Reproductive Capacity

It is the responsibility of the Operator to ascertain the patient's pregnancy status before making the exposure.

