

Document Control

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1. Introduction

Under the IR(ME)R 2017 regulations, no person shall carry out a medical exposure to ionising radiation unless:

- The exposure has been justified by a Practitioner.
- The exposure has been justified by a Practitioner or, under certain circumstances the Operator (see section 5 below).

A Practitioner is a registered healthcare professional who is entitled, in accordance with the employer's procedures, to take responsibility for an individual medical exposure. The primary role of the Practitioner is to justify medical exposures

Any Consultant Radiologist or trainee Radiologist employed by NDHT can justify and authorise medical exposures.

Consultant Cardiologists are entitled to justify medical exposures for the purpose of Cardiac CT scans.

HPCP registered Radiographers can also justify and authorise medical exposures under a written local agreement with the Lead Clinician for Radiology (see section 5).

2. Purpose

The Standard Operating Procedure (SOP) has been written to: Clarify the procedures for the Justification and Authorisation of medical exposures to ionising radiation.

3. Scope and Location

This SOP applies to Practitioners and Operators who justify and/or authorise medical exposures for radiology services within the Northern Devon Healthcare NHS Trust (NDHT)

- General X-ray Department at NDHT
- CT Scanning Department NDHT
- Peripheral X-ray Departments at Bideford and Ilfracombe.
- Operating theatres at NDHT

4. Equipment

- Radiology request forms
- Radiology Information System (CRIS)
- Imaging Protocols
- Practitioner / Operator Certificate of Entitlement

5. Procedure for 'Justification and Authorisation'

Before a registered radiographer can be entitled by the Lead Clinician for Radiology to act as a practitioner in order to justify medical exposures, the radiographer's statutory and mandatory training (including IRMER training modules on STAR) must be up to date and recorded on the departmental training log. CPD records and imaging and equipment competency records must also be up to date and their IR(ME)R Awareness Declaration form signed and filed electronically on the Clinical Governance drive.

Newly appointed, experienced radiographers (not in preceptorship) must have also completed the Radiology Department Induction Programme and signed an IR(ME)R Awareness Declaration form to confirm that they have read and understood their responsibilities under the regulations.

Newly qualified Radiographers will be entitled to justify requests for medical exposures upon satisfactory completion of their preceptorship period, including departmental induction and competency assessments and signed IR(ME)R Awareness Declaration form.

When all of the above requirements have been met, the Lead Clinician will sign and date individual Certificates of Entitlement, enabling registered radiographers to act as 'Practitioners' to justify general imaging requests and /or CT scan requests as specified in the local imaging protocols.

Arrangements in Theatre:

Radiographers who are identified as IR(ME)R practitioners, take responsibility for medical exposures in theatres. This resolves the issue of whether or not surgeons are 'adequately' trained for the IR(ME)R practitioner role. However, if a surgeon having completed a recognised IR(ME)R training, has been entitled to act as a Practitioner by the Employer and wishes to fulfil this duty for a specified procedure, the radiographer must record this information on the patient's CRIS record.

Justification

The Practitioner must take into account the clinical information provided by the Referrer. This should be carefully considered in order to avoid unnecessary exposures. There must be sufficient information on the request form to:

- Identify the patient correctly
- Give sufficient clinical history and indicate the clinical question to be answered so that the potential benefit of the exposure may be assessed and weighed against the detriment the exposure may cause
- Assess the efficacy, benefits and risk of available alternative techniques having the same objective but involving no or less exposure to ionising radiation
- Give consideration to the specific objectives of the exposure and the characteristics of the individual involved
- Indicate where relevant that the question of potential pregnancy has been considered
- In the case of a female aged 12-55, the local procedure for women of reproductive capacity must be followed for emergency referrals when it may not be possible to contact a Radiologist.
- The form must bear a recent date, a legible signature and contact number

Note:

Radiographers acting as referrers must in addition to the above, take into account the total potential diagnostic benefits, including the direct health benefits to the individual and the benefits to society, of the exposure.

Authorisation

Where it is not practicable for a practitioner to do so, authorisation may be undertaken by a properly entitled operator (radiographer or assistant radiographer practitioner) in accordance with written departmental imaging protocols.

Responsibility for justification remains with the practitioner who has provided the guidelines but the operator is responsible for the proper interpretation of these guidelines.

If the practitioner or operator is aware at the time of authorisation, that a recorded clinical evaluation shall not result from the exposure, then the exposure must not be authorised and cannot take place.

Operator Guidelines for Authorisation

Only entitled operators may undertake authorisation, using local imaging protocols and exposure guidelines for reference. A list of entitled Operators is held by the Radiology Governance Lead and is available on the Radiology G:drive.

Guidelines and entitlements are clearly identified on local imaging protocols and all entitled operators **MUST** be issued with a 'Certificate of Entitlement' signed by the Lead Clinician to confirm their entitlement to carry out this task.

Referrals will only be accepted from recognised referrers if the referral criteria on the request form are in accordance with local imaging protocols (which are based on those published by the Royal College of Radiologists booklet and I-Refer). A list of entitled referrers is held by the Radiology Governance Lead and is available on the Radiology G:drive.

Entitled operators must check the clinical details on the patient request form against the appropriate imaging protocol and if the details match the criteria, the operator initials the request form and completes the CRIS record to designate that the medical exposure has been authorised.

There must be a check for recent /previous imaging before the exposure can be authorised and if necessary, a check in the patient's notes for recorded referrer assessment of findings of recent imaging.

If the radiographer who authorises the exposure is not the same person who will undertake the exposure, the authorisation procedure **MUST** be recorded on CRIS with any additional notes added in the comments box provided in the event history.

Referrals which do not fall within the departmental guidelines issued by the practitioner cannot be authorised by an operator and must be referred to a practitioner for justification.

Where the referral criterion has not been met and it is impractical to consult a Practitioner, the request form must be returned to the referrer. It is then the referrer's responsibility to either cancel the request or supply further clinical information.

Prior authorisation: Operators **MUST** make an authorisation entry within the Radiology Information System (CRIS) prior to the exposure taking place.

Additional Notes for Justification and Authorisation

Research Exposures

Research exposures must have been approved by the Local Research Ethics Committee (LREC) before the exposure can take place.

Guidance on the establishment, composition and functions of Local Research Ethics Committees (LRECs) is provided by the Health Departments. The guidance states that all research in the UK should be approved by a LREC, whether or not it has been submitted also to a Multi-Centre Research Ethics Committee (MREC). The LREC can recommend that research is undertaken with a proviso that a certain dose is not exceeded.

For a medico-legal exposure, the exposure must fall within the local procedure guidelines.

Medico Legal Exposures

Medico-legal exposures must be justified and authorised by a Practitioner

LMP Pregnancy Checks

In the case of a female aged 12-55, the local procedure for women of reproductive capacity must be followed.

Justification

In order to justify an exposure, the Practitioner must take account of the following:

1. The specific objectives of the exposure and the characteristics of the individual involved.
2. The potential diagnostic benefits to the patient.
3. Any detriment that the exposure may cause
4. The efficacy, risks and benefits of alternative procedures having the same objective but involving no or less exposure to ionising radiation.
5. Must ensure that the request is from a recognised Medical, Dental or NonMedical Referrer.

When considering these points, the practitioner must pay special attention to:

1. Exposures on medico-legal grounds (please see section 'Medico-legal and non-accidental injury requests' – follow link for Research Exposures No. 3 above).
2. Exposures that have no direct health benefit to the patient (research /medico legal as above)
3. The urgency of the exposure where pregnancy cannot be excluded taking into account of the exposure of both the expectant mother and unborn child.

6. 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

Ionising (Medical Exposures) Regulations 2000. Statutory Instruments 2000 No 1059 –

<http://www.opsi.gov.uk/si/si2000/20001059.htm>

IRMER – Ionising Radiation (Medical Exposures) Amendment Regulations 2006
http://www.opsi.gov.uk/si/si2006/uksi_20062523_en.pdf

7. Associated Documentation

Northern Devon Healthcare NHS Trust Policies for:

- IR(ME)R Procedures SOP – Scope of Entitlement
- IR(ME)R Procedures SOP - Making a referral for diagnostic imaging
- Plain film radiographic protocols