GenesisCare UK IR(ME)R Employer's Procedures (GCEP) (UK)

1. Introduction

1. All persons must be aware of GenesisCare's Radiation Safety - Organisational Arrangements and Responsibilities (RP-POL-005) which covers legislative requirements to protect patients - Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R) and members of staff and the public – Ionising Radiations Regulations 2017 (IRR).
2. Under the IR(ME)R, the employer is required to have set down certain written procedures, at minimum covering those aspects listed in Schedule 2 of the Regulations. These GenesisCare UK procedures, limited to the topics in Schedule 2, are given the term GenesisCare UK IR(ME)R Procedures – GCEP (GC IR(ME)R Employer's Procedures).
3. All referrers, practitioners, and operators, requesting, justifying, or carrying out medical exposures, are bound by these Procedures. It will be noted that any failure to comply with the Procedures is a serious matter and may render GenesisCare and/or individual liable to prosecution under the legislation.
4. It will be noted that these GenesisCare-wide Employer's Procedures (EP's) apply to all medical and non-medical exposures and need to be read in conjunction with the modality specific EP's which give further detail of other specific IR(ME)R requirements.
5. IR(ME)R training requirements are outlined in the Induction, Training and Technical Competency Policy Clinical and Clinical Administrative Staff (UK) (TRN-POL-060) and associated IR(ME)R specific training documents
6. On behalf of the Employer, the Heads of Service should design and implement a suitable and sufficient training program for all practitioners and operators.

2. Patient Identification Procedures Schedule 2: 1(a)

1. Although patients may be identified at more than one stage in the process, the responsibility for a final check on the identity of the patient is by the operator undertaking the exposure and MUST be prior to the exposure taking place.
2. Patient identification must be subject to a 3-point patient identification process e.g. full name, address, and date of birth. Identifying questions must be active with a positive verbal response given by the patient i.e. ask the patient to state their full name.

3. In addition to positive identification of the patient, questions confirming the type of radiological procedure are required to be asked. These will include such questions as site, laterality and whether this exam has been carried out previously. Confirmation of these details must be recorded.
4. Where the patient is unable to respond personally, then the final check of identity will be made with accompanying parent(s)/person(s) and/or additional confirmation will be sought where appropriate with a form of photographic identification (e.g. Passport). If the patient cannot understand English and there is any possibility of incorrect identification, then assistance with interpretation must be sought before any treatment is delivered. Please refer to Interpretation Policy (COR-POL-008).
5. Any extension of this procedure for patient identification at departmental level is reflected in the modality specific EP's and Departmental Procedures (DPs).

3. Referrers, Practitioners, Authorisation and Operators Schedule 2: 1(b)

3.1. Referrers and Referral Criteria

1. Referrals for diagnostic examinations involving radiation exposures are accepted from the following:

    a. Registered doctors with valid practising privileges at GenesisCare UK and;
    b. In accordance with other health care professional referrers by special arrangement and departmental protocol

2. In the case of Radiotherapy treatment referrals, the clinical Oncologist or Neurosurgeon will act as the referrer and practitioner. Radiotherapy treatment referrals are only accepted from entitled Practitioners who have been suitably trained and granted practising privileges to act as a referrer within GenesisCare.

3. All paediatric referrals for patients under the age of 18 must be rejected, GenesisCare does not accept Paediatric referrals for any form of radiological examination or radiotherapy treatment.

All medical exposures within GenesisCare are required to be justified, those justifying the exposure are **Practitioners** and are responsible for justification. The practitioner remains responsible for justifying the individual referral, considering the benefit and risk associated with the exposure, and considering the clinical information supplied by the referrer.

Practitioners will be identified within the modality specific EP's and named individuals are stored within the relevant entitlement register.

3.2. Authorisation

All medical exposures within GenesisCare are 'authorised' with an appropriate signature on the referral form (booking form) or by electronic signature on a computerised administration system. Those who authorise exposures are **Operators** for that task and are trained accordingly.

Where it is not practicable for an exposure to be authorised by a practitioner, they will be performed by an operator under written procedures authorised by the practitioner, these are outlined in the modality specific EP's and DPs.

3.3. Practical Aspects (IR(ME)R Operators)

Practical aspects of medical exposures are wide-ranging. Trained persons carrying out such activities are **Operators** for that purpose. They have the responsibility for ensuring that the practice under their control is carried out in accordance with their professional or other relevant training, national guidance, accepted good practice and in accordance with the modality specific EP's and DPs. Practice is aimed at ensuring doses are as low as reasonably practicable bearing in mind the therapeutic purpose of the procedure and minimising the likelihood of any Significant Accidental or Unintended exposures. Operators for the specified task(s) will be identified and named within the relevant Entitlement Register. Below is an overarching list of operators:

- Radiologist
- Therapy radiographers
- Diagnostic radiographer
- Clinical Scientist (Radiotherapy)
- Clinical Scientist (Nuclear Medicine and Diagnostics)
- Medical dosimetrists
- Nuclear medicine technologists
- Medical Physics Experts (MPE's)
- Radiopharmacy Staff
- Diagnostic Health Care Assistants

4. Pregnancy and Breastfeeding Enquiries Schedule 2: 1(c)

GenesisCare does NOT accept referrals/bookings for any patient under the age of 18

1. For all patients of childbearing capacity between the ages of 18-55 years old, GenesisCare have the responsibility to put in place a written procedure to make enquires as to whether an individual undergoing an ionising radiation exposure is or may be pregnant or breastfeeding.

2. The **Referrer** is responsible for considering a patient's pregnancy or breastfeeding status at the time of making the referral for ionising radiation exposure.
3. The **Practitioner** remains responsible for justifying the individual referral/booking, considering the benefit and risks associated with the exposure, considering the clinical information supplied by the referrer.
4. All **Operators** must ensure prior to the authorisation of the radiation exposure taking place, that all patients of childbearing capacity are asked the question of 'are you or might you be pregnant?' where an active response is received from the patient to confirm if there is any possibility of pregnancy this MUST be documented according to specific modality procedures.
5. When the patient is unable to personally respond to the operator, advice must be sought from the referrer or another health care professional involved in the patient's care. The exposure must not proceed until pregnancy status is clearly established.
6. Any extension of the procedure to identify pregnancy status at departmental level is reflected in modality specific EP's and DPs.
7. If the patient is known to be pregnant or there is a possibility of pregnancy the operator shall follow the pregnant patient protocol in the DPs with the aim of minimising the dose to the foetus.

5. Quality Assurance Programme Schedule 2: 1(d)

All medical radiological equipment must be subject to a suitable and sufficient Quality Assurance (QA) programme to ensure equipment is operating safely and within acceptable tolerance limits as defined by manufacturer and national guidance.

The relevant Head of Service should ensure that this programme is in place and Operators undergo suitable training to complete these tasks.

All QA programmes should be subject to routine audit and review, where it is the responsibility of the service line committees to:

1. Confirm that the procedures are effective and appropriate.
2. Review audits that are performed by the departments and support any changes that may be required.
3. Ensure that a report is made to the employer via the minutes of the UK Radiation Safety Committee.

All quality assurance procedures must be accurate, appropriate, up-to-date, and meet the objective. To ensure this, all policies and procedures will be contained within the GenesisCare documentation quality system and will be available to all staff members to access via the UK Policy Centre.

Policy and documentation management is overseen by the GenesisCare Quality Team.

6. Assessment of patient dose Schedule 2: 1(e)

1. For every medical exposure, the operator shall ensure that a record is kept of the type of investigation and other factors relevant to patient dose. This includes an estimation of the effective dose to the patient that can be made. Records will be kept for an appropriate length of time as stipulated in the Retention Records Management Policy (IG-POL-032).
2. For radiography including dental and mammography, relevant factors will include at minimum the examination and projection(s), number of exposures (and will also include kVp/mAs/patient thickness (mammography), where practicable). The factors will be recorded on the request form and on the computerised administration system where practicable.
3. For fluoroscopy, the examination type, dose area product (where fitted) and screening times must be recorded in the screening book (and/or on the computerised administration system where applicable).
4. For CT examinations the Dose Length Product (DLP) or Computed Tomography Dose index (CTDi) are recorded onto the computerised administration system.
5. For all exposures involving administration of radionuclides the nature of the administration including activity of the radionuclide is recorded in the Excel document that is kept for that purpose and/or in the computerised record system and in the patient's notes.
6. For molecular radiotherapy (Theranostics), exposures of target volumes should be individually planned, and their delivery appropriately verified; taking into account that doses to non-target volumes and tissues must be as low as reasonably practicable and consistent with the intended radiotherapeutic purpose of the exposure.
7. In cancer treatments following each administration of radioactive substances, the absorbed dose to the tumour and to non-target volumes and tissues, should be measured and recorded to permit subsequent optimisation of total doses.
8. For treatment of benign conditions or, where direct measurements are impossible, absorbed doses should be calculated or estimated and recorded in MOSAIQ
9. For radiotherapy, all treatment plans will be individually planned, and records made of the dose to all relevant Target Volumes (TV's) and Organs At Risk (OAR's). Clinical protocols are in place for all treatment sites.

7. Diagnostic Reference Levels Schedule 2: 1(f)

1. Local Diagnostic Reference Levels (LDRL's) must be established for all routine examinations and subject to regular audit and benchmarked against National Diagnostic Reference Levels.
2. LDRL's must be made available to the Operator and laid down in DPs to evaluate individual patient exposures and aid optimisation.
3. The relevant levels, detailed in the DPs, will be reviewed at least every 3 years from the point of commissioning, by the relevant departments in conjunction with the Medical Physics Expert (MPE) and endorsed by the Radiation Safety Committee.
4. In nuclear medicine the local reference levels relate to administered activity and are based on the ARSAC guidance 2020
5. When best practice regarding diagnostic and technical performance is applied, it is not expected that doses for average sized patients will exceed the National diagnostic reference dose levels. Once local reference levels have been established, subsequent audits are expected to be within ±20% of these values. However, if a survey of doses for a representative sample of standard-sized patients significantly varies from local reference levels, a review will be undertaken to evaluate the reasons, so that corrective action can be taken with a view to optimising doses.
6. Local Dose Reference levels must be established for all radiotherapy planning CT examination following the same process definition above for Diagnostic Reference levels.

8. Research Procedures Schedule 2: 1(g)

Proposals for research studies involving medical exposures must be assessed by relevant MPEs and local practitioners. Dose constraints are identified in the research protocol and if a site cannot comply with these then it cannot be part of the research.

DPs in line with IR(ME)Rare developed and available to support any Research Procedures

When any radiation exposures are required as part of that research study a single ethical opinion will have been obtained for the study in line with the requirements of the Medicines for Human Use (Clinical Trials) Regulations 2004 and in accordance with the latest guidance on Approval for Research involving Ionising Radiation.

9. Information to patients undergoing treatment or diagnosis Schedule 2: 1(h) & (i)

1. Patients undergoing any radiological procedure will be given appropriate information, prior to the exposure taking place. The information will be provided to the patient in the form of patient information and where appropriate by the referrer this information will clearly explain the risks and benefits of the procedure to the patient.
2. A consent process must be in place for all radiological therapy procedures where the relevant consent form must be reviewed and signed by both the patient and an entitled operator before any procedure takes place. It is the operator's responsibility to ensure that consent has been obtained before performing any therapeutic procedure.
3. Patients undergoing treatment by radioactive medicinal products will be given appropriate patient information and asked to complete the consent form for the procedure. The Practitioner is responsible for explaining the risks and benefits to the patient.

10. Medical Exposure Evaluation (Examination Report) Schedule 2: 1(j)

1. For the purposes of diagnostic radiology, exposures will 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 will not be carried out.
2. For the purposes of Radiotherapy, all exposures performed must contribute to the planning or delivery of the patient's therapeutic treatment. Before any radiological exposure is performed, it is the responsibility of the operator to ensure that all necessary checks have been completed to allow the therapeutic delivery to proceed. The necessary check to ensure this will be defined in DP's.
3. For most exposures this is a routine procedure with a practitioner 'report' produced and returned to the referrer for inclusion in the patient's notes.
4. Where necessary, estimation of dose can be made by reference to the factors recorded on the request form and/or computerised radiology administration system.
5. For a course of treatment, the referring clinician will record the evaluation in the patient's notes and at any follow up appointment. A letter will also be sent at the end of a course of treatment to the patient's GP with a summary of the evaluation.
6. Where 'unreported' exposures are returned to the referrer based outside GenesisCare, a letter on headed paper will accompany the images advising the third party of the need to record the diagnostic findings in the patient's notes. A copy of dose factors should be supplied where appropriate.

11. Accidental or unintended exposures Schedule 2: 1(k)&(l)

1. It is important to ensure that the probability and magnitude of accidental or unintended doses to patients from radiological practices is reduced so far as reasonably practicable.
2. With this aim in mind operators must note that all practical aspects will be conducted with due regard to minimising the probability of accidental or unintended (i.e. an exposure that was not intended, as a result of mistaken identification or other procedural failure) exposures of patients.
3. Where such accidents or unintended exposures occur, the operator must follow the procedures for reporting significant accidental or unintended exposures according to the Incident and Risk Management Policy (QR-POL-170). The operator must inform the Centre Leader/ Professional Head of Service/ Medical Physics Expert (MPE) and the Radiation Protection Adviser (RPA) as soon as practicable.
4. All incidents or near misses must be raised on Datix on the same working day that the incident occurs as per the Incident and Risk Management Policy (QR-POL-170).
5. For all incidents, an immediate investigation is performed by an investigation lead, the investigation lead is appointed, and a suitably appointed MPE, according to the Incident and Risk Management policy (QR-POL-170). These leads will quantify the clinical impact of the error and a correction strategy formulated if required.
6. Lessons learnt are shared and discussed at the various service specific sub committees, the UK RaSC and clinical governance committee where relevant and disseminated through the organisation using multiple communication methods, including daily huddles, team meetings and rapid alert notifications.
7. Compliance is monitored through the national audit programmes in place and findings discussed at the relevant governance committee.
8. Where such incidents occur a Root Cause Analysis investigation will be undertaken by the operator in conjunction with the practitioner, Head of Service and RPA / MPE aimed at:

    I. Establishing what happened.
    II. Identifying the failure.
    III. Deciding on remedial action to minimise future occurrences.
    IV. Estimating the dose(s) received.
    V. Identifying the error to the wider team via a Rapid Alert or other means of communication if required.
    VI. Informing the patient as per Duty of Candour Policy
    VII. Reporting the incident or near miss to external agencies if appropriate.

9. In conjunction with the relevant Head of Service (Head of Physics, Head of Theranostics and Imaging) and the MPE it will be determined if the incident is reportable to the CQC under the guidance documents "Significant accidental and unintended exposures under IR(ME)R Guidance for Employer's and duty-holders (June 2019)
10. In the event of a reportable incident patients will be informed (or their representatives where appropriate) of the incident. The practitioner and referring clinician will normally be involved.
11. With these procedures in mind, minimising the possibility of unintended doses or doses much greater than intended is emphasised in DPs, local rules and during training.
12. In the event of any external auditing or regulatory bodies (such as the Health and Safety Executive, Care Quality Commission, Environment Agency, Counter Terrorism Services Agency, Office for Nuclear Regulation) contacting or visiting GenesisCare it is the responsibility of that Department to inform The Head of Service, the Chair of the UK RaSC and the UK Leadership Team.

12. Non-Medical (including medico-legal) exposures Schedule 2: 1(m)

Non-medical imaging requests for Diagnostic Imaging, Nuclear Medicine and Radiotherapy Procedures are NOT undertaken at GenesisCare.

13. Carers and Comforters Schedule 2: 1(n)

1. Carers and Comforters (C & C's) are individuals who knowingly and willingly incur an exposure to ionising radiation by helping, other than as part of their occupation, in the support and comfort of individuals undergoing or having undergone an exposure.
2. Persons supporting a patient who are in attendance as part of their employment (GenesisCare staff) are not classed as C&C's. All processes will be the same as for a C&C to ensure that these individuals are fully aware of the exposure and doses are kept As Low As Reasonably Practicable (ALARP). Doses to these individuals must be below the public dose limit as they are not deemed radiation workers.
3. If a person is acting as a C&C, sufficient information must be provided to that individual to ensure that they are aware of the small risks involved in aiding in the procedure.
4. It must be documented that the person has agreed to act as a C&C. This process is outlined in the departmental procedures.
5. All efforts to reduce the dose to C&C's must be made including the provision of PPE and adequate instruction.

6. A dose constraint of 1mSv has been set unless otherwise stated in local DPs.
7. C &C's shall not be permitted for any patient referred for Radiotherapy.

14. References

- Ionising Radiation (Medical Exposures) Regulations 2017 (IR(ME)R Amendments 2018
- IR(ME)R Employer's Procedures – Radiotherapy (RP-SOP-001)
- IR(ME)R Employer's Procedures – Nuclear Medicine (RP-SOP-056)
- IR(ME)R Employer's Procedures – Diagnostic Imaging (RP-SOP-077)
- Incident and Risk Management Policy (QR-POL-170)

15. Appendix

Appendix 1: Staff Declaration Form

16. Signatures

Medical Physics Expert: (Royal Surrey County Hospital)

Signed: 

Role: Radiation Protection Adviser

Date: 1st July 2020

Chair, Radiation Safety Committee:

Signed: 

Role: Head of Medical Physics UK

Date: 1st July 2020

Deputy Chair, Radiation Safety Committee

Signed: 

Role: Head of Theranostics and Imaging UK

Date: 1st July 2020

Revision History

Version	Date Created	Created By	Description of change
1.0	June 2020	Emma Spellman Head of Theranostics and Imaging	New Document

Appendix 1: Staff Declaration Form

By signing this for, I confirm that I have read and understood **issue 1.0** of the GenesisCare IR(ME)R Employer's Procedure, and that I undertake to ensure full compliance to it.

Full Name	Job Title	Signed	Date