The Christie NHS Foundation Trust

IR(ME)R inspection report

Date of inspection:
31 May 2023

This report sets out the key findings from our recent inspection of compliance with the Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R). We based this on a combination of evidence submitted, including previous statutory notifications and any other intelligence available to us.

How we inspected

CQC inspectors conducted a virtual announced inspection of compliance with the Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R) of the radiotherapy service at The Christie NHS Foundation Trust.

Prior to inspection, the service completed an Inspection Self-assessment Questionnaire. We requested and received copies of relevant documents, including the employer's procedures (EPs), equipment inventory, radiation protection governance documentation, clinical audit as well as study of risk and radiation incident information. We explained the post-inspection process after receiving the completed questionnaire.

As part of the inspection process, we held remote discussions on 31 May 2023 with various staff of all grades.

Summary of findings

Staff we spoke with were engaged, experienced, and cited a positive culture within the department and wider organisation, with a supportive and visible executive team who reinforced compliance with the regulations.

Discussions with clinical staff showed that procedures and protocols were reflective of the day-to-day running of the department.

The service was supported by medical physics experts (MPEs), who were proactively involved in optimisation, quality assurance matters, training and worked collaboratively to fulfil the requirements of the regulations.

EPs were available and reflective of those required under Schedule 2. However, some parts were policy driven and did not reflect actual procedure, with multiple references made to local procedures.

What we found

Service Overview

The service was the largest provider of radiotherapy in the NHS and the sole provider of radiotherapy for Greater Manchester. The service undertook radiotherapy across four sites.

The service undertook approximately 93,496 fractions per year and was a specialist commissioned service for stereotactic ablative radiotherapy (SABR).

The radiotherapy service consisted of 15 linear accelerators (linacs), 6 computed tomography (CT) scanners for radiotherapy planning, a kilovoltage superficial unit and an MR linac. All linacs used advanced on-board imaging for image guided radiation therapy (IGRT) for external beam radiotherapy.

Vacancies across the service did not impact on the ability to provide a comprehensive service.

The service treated paediatric patients and undertook research. Screening patients were not treated, and non-medical activity was not undertaken.

Management/Governance Structure

The IR(ME)R employer for the radiotherapy service was the Chief Executive Officer (CEO).

The service demonstrated the management arrangements for radiation protection matters with an organisational chart. This showed assurances in relation to risk and governance were managed through the trust's risk and quality governance structure. This operated at directorate, divisional and trust level.

Risks on a trust level were discussed at the Risk and Quality Governance Committee as well as the Radiation Protection and Medical Exposure Committee. Divisional level risks were discussed at the Divisional Quality and Divisional Board meetings. On a directorate level, risks were discussed at the Radiotherapy Governance meeting.

We were provided with the Ionising Radiation Protection and Medical Exposure Policy which detailed how radiation protection assurances were provided through a framework and managed through the Radiation Protection and Medical Exposures Committee.

All risks were managed as set out in the trust's Risk Management Strategy and Policy. The policy set out the responsibilities, process, and approach to management of risk within the trust. Risks relating to ionising radiation were owned and managed through the radiotherapy department. Escalation of risks took place in line with the trust Risk Management Strategy and Policy.

Procedures, Protocols and Quality Assurance Programmes

The service had all written procedures required by Schedule 2 which covered the full range of service delivery. However, some of the procedures read more as a policy statement with no clear description of actual process for clinical staff to follow. EPs referenced multiple local standard operating procedures which outlined these processes. Staff we spoke with explained how these could be accessed.

The radiotherapy service had an electronic quality management system (QMS) where all staff were able to access procedures and protocols.

Procedures and protocols were available to all duty holders. Effective management of key

documents was outlined in the Ionising Radiation Protection and Medical Exposure Policy.

Changes made to procedures were communicated by a monthly summary notification. Critical safety changes were additionally communicated via memos which included read and sign requests or safety triangle alerts. Managers audited practice regularly to check that it was in line with procedures.

Written protocols were in place for all standard techniques. We saw evidence that protocols were reviewed, still reflective of practice and tracked by an audit schedule.

Referrals and Referral Guidelines

All patients were referred and reviewed at appropriate multi-disciplinary team (MDT) meetings. Patients were then reviewed by a consultant clinical oncologist with the intention of consent and referral for radiotherapy. Referrals were received in electronic format through the trust's patient information system.

All referrers could access referral guidelines which were written and reviewed regularly. The chair of each of the disease groups drew up referral criteria. Chairs worked with the Division of Networked Services and Department of Clinical Oncology. Referral guidelines were made available to all clinicians acting as referrers for radiotherapy treatment via the trust's QMS.

Clinical guidelines were in place for each patient type, these were maintained and accessible in the QMS. Each guideline detailed and linked to the relevant work instructions that covered the key area for the delivery of radiotherapy.

The service had a process to manage non-medical referrers, with a limited scope of practice relevant to their clinical role.

Carers and Comforters

The use of carers and comforters to support patients undergoing radiotherapy examinations was not justified. However, exposure of carers and comforters was clearly defined within the EPs and alternative methods for comfort or immobilisation of patients during treatment were available.

Pregnancy and Breastfeeding

Staff checked whether patients were breastfeeding or might be pregnant and raised awareness of the effects of ionising radiation in those circumstances.

When reviewing the 'Guide to Checking the Pregnancy Status of Patients of a Childbearing Age' work instruction referenced within the EPs, we noted incorporation of new professional body guidance surrounding inclusivity of individuals of childbearing potential. However, the EPs referenced enquiries of females rather than the inclusive terminology used within the Regulations.

Research

The service had safe dose constraints for research participants and ethical approval for all studies. Staff were aware of active research trials and their requirements.

The service had a Research Governance Group (RGG) which maintained oversight of all research sponsored by the trust. Radiotherapy clinical trials were reviewed by a multidisciplinary team and ratified at the Radiotherapy Steering Group (RTSG).

Trial protocols and guidelines were uploaded onto a separate clinical trials section within the

QMS. Staff we spoke with confirmed that these were easily accessible.

Staff were kept informed of radiotherapy trials within the department by speciality team specific research meetings, newsletters, information sessions, the RTSG and implementation group meetings.

Trials conducted within the radiotherapy department had an in house ‘factsheet’ which highlighted the radiotherapy aspects of the trial protocol and the difference between the radiotherapy required in the protocol and departmental standard of care.

Patients on clinical trial had their participation flagged on the electronic patient record and in the radiotherapy record and verify systems. Staff we spoke with confirmed that trial patients required sign off on systems prior to commencing treatment.

Clinical Audit

Members of different staff groups undertook clinical audits to assess and improve the quality of the service.

The service had a procedure for undertaking clinical audit, and we were sent some recent examples. Audit topics included the impact of COVID on radiotherapy training.

Clinical audits were reviewed and discussed within clinical disease groups and at trust mortality and morbidity review meetings.

Incidents

The service had a system for recording the occurrence and analysis of radiation incidents. Incidents were analysed to identify trends and were discussed at radiation governance meetings.

The service had not clearly defined clinically significant within the EPs. However, we saw reference of procedures to inform the referrer, practitioner, and patient if a clinically significant unintended or accidental exposure occurred, and the outcome of the investigation clearly outlined within the ‘Procedure for Incidents and Complaints.’

We noted that the link to guidance on significant unintended or accidental exposure was out of date.

We checked a sample of incident records and saw that, of those checked, all had been appropriately investigated and contained enough detail. Where required, incidents had been reported to the enforcing authority, and the outcomes shared. Dose assessments were routinely undertaken during these investigations.

The service had a study of risk in place for radiotherapeutic practices. On review of this we noted it to contain the principal areas of local risk of unintended or accidental exposure.

Duty Holders

Practitioners and operators were entitled appropriate to their role as part of the employer's procedures. Both groups understood their responsibilities and the need to cooperate with other professionals involved in medical exposures. The department kept an up-to-date list of all duty holders in the department, along with their job title and role under the regulations.

When questioned, staff were able to verbalise where this was located on the QMS.

Justification and Authorisation

The service had a documented process that defined clearly who undertook justification and authorisation, and what factors must be considered. Audits of requests and referrals showed that the process was followed.

Treatment exposures including verification imaging were authorised by the approval of planning documentation in the patient information system relevant to the approved treatment at the plan approval stage by a practitioner.

Non-standard verification images, such as those taken following re-setup of a patient or due to patient movement, could be authorised by appropriately trained radiographers or once verbal authorisation from a clinician was sought. This was documented accordingly within the record and verify system.

Non-Medical Imaging

The radiotherapy services did not accept referrals for any non-medical imaging exposures. This was documented within the EPs.

Optimisation

The service had a process for the optimisation of patient doses, including a rolling programme and regular audits against diagnostic reference levels.

The service undertook optimisation work led by the imaging physicist in radiotherapy. We were told the imaging physicist worked with radiographers to optimise and review all imaging protocols. Staff were able to describe the principles of optimisation and gave examples of how doses could be kept as low as reasonably practicable (ALARP).

Established protocols were in place to support practitioners and operators to ensure doses were ALARP. On-treatment verification imaging protocols were defined during equipment commissioning. The service undertook regular audits of imaging doses to continually monitor doses delivered to patients.

There were separate protocols in place for paediatric patients. These had been set up with the manufacturer and were audited regularly on each scanner. Fast lower dose pre-sets were preferentially used for paediatric radiotherapy verification imaging.

Each patient was discussed in dedicated pre-planning meetings as appropriate to ensure the protocol matched the clinical needs of the patient.

Each individual exposure was optimised to the patient, with target volumes being individually planned. Non-target volumes and tissues such as organs at risk (OARs) were consistent with the intended radiotherapeutic purpose and dose was kept ALARP. Offline review of every onset image was undertaken to ensure consistency with established processes.

The service utilised dose reference levels (DRLs) for dose optimisation of standard exposures in planning and verification. These were audited and compared to the published national DRLs for radiotherapy planning exposures.

Patient doses were recorded in the service’s information and image management system.

Clinical Evaluation

The service ensured clinical evaluations, including dose information, were recorded for every patient exposure, by staff trained to do so. Staff undertook weekly checks of all patients currently on treatment, and these were conducted in line with local administrative tasks checking procedures.

Assessment of patients' acute and long-term side effects were ascertained during treatment and at follow-up.

Operators conducted clinical evaluation of verification exposures following acquisition as specified within local procedures. This included assessment of image quality to inform subsequent treatment exposures.

National Dose Surveys

The service provided data on patient doses as part of national dose surveys.

Medical Physics Expert

The radiotherapy service had several entitled MPEs, each with specified job descriptions for appointment.

There was always close involvement of an MPE in all aspects of the radiotherapy service.

The expertise of MPEs was relevant to the scope of their support to the department and we were assured that they were appropriately involved in all matters set out in regulation 14, as well as involvement with radiation safety committee meetings. We saw evidence of MPE audits of departmental compliance with the regulations, which highlighted any areas where practice could be improved.

The day-to-day involvement of physics in the service was well managed and clinical staff felt they were able to seek their support easily.

Equipment

The service regularly checked the performance of all radiological equipment, and records showed that this happened in line with professional guidance.

Competent technologist staff did daily and weekly control (QC) tests, with physicists completing other QC checks.

All radiotherapy equipment was managed through a medical device management system and QC results were managed using spreadsheets. These spreadsheets showed performance over time so trends could be identified and flagged to the user any results outside tolerance.

All imaging equipment had regular maintenance as part of a managed equipment service, with documented handover of equipment and post-maintenance QC checks undertaken where required.

The service's inventory of radiological equipment included all required information, and all equipment was capable of reading out, recording and transferring dose information.

Training

The service had a procedure which detailed how training of practitioners and operators was managed, and how competency was achieved and maintained.

The service used training records to ensure that all practitioners and operators, including agency/bank/locum staff, were adequately trained and undertook continuing education and training.

Staff we spoke with provided numerous examples of training courses and continuing professional development (CPD) opportunities they had attended. Staff stated they had protected time allocated for CPD and received annual IR(ME)R update training.

Workbooks and assessments were a mixture of electronic and paper based. Completed documents were scanned and stored in individual training inventories on a shared drive.

The service held additional databases and spreadsheets across radiotherapy to identify numbers of staff who required training and to support departmental training needs analysis.

Training records for medical physics staff were held in a global training database and clinical oncology operator records were stored in a separate database.

Areas for improvement

The following areas are where a breach has been found which did not justify regulatory action. To prevent it failing to comply with legal requirements in future, or to improve the quality of services, the employer should take the following actions to comply.

Regulation	Action required
6 **Employer's Duties**	The employer must ensure that written procedures in respect of those matters described in Schedule 2 are reflective of local practice and that they contain sufficient detail for all duty holders.
6(1)(a) **Employer's duties**	The employer must ensure that clinically significant incidents are clearly defined within the employer's procedures.
6(1)(a) **Employer's duties**	The employer must ensure that procedures for making pregnancy enquiries are inclusive of all individuals of childbearing potential.

What happens next

In response to the actions required, as above, we require the employer, to provide an action plan to be **submitted within 6 weeks of the date** on this letter. This action plan should set out how the requirements are being addressed and within what time scale, and should be sent to irmer@cqc.org.uk. Where we have undertaken any enforcement action, this will be managed through separate correspondence.

If we are satisfied with the action plan submitted, we will write to you to confirm the inspection process has been concluded. We will continue to monitor compliance through our usual intelligence gathering.