

Heart & Lung Imaging Limited

Heart & Lung Imaging Limited

Inspection report

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This report describes our judgement of the quality of care at this service. It is based on a combination of what we found when we inspected, information from our ongoing monitoring of data about services and information given to us from the provider, patients, the public and other organisations.

Ratings

Overall rating for this location

Good 

Are services safe?

Good 

Are services effective?

Inspected but not rated 

Are services responsive to people's needs?

Good 

Are services well-led?

Requires Improvement 

Summary of findings

Overall summary

This is the first time this service had been inspected. We rated it as good overall because:

- Staff had training in key skills, understood how to protect patients from abuse, and managed safety well. Staff assessed risks to patients, acted on them and kept good care records. The service had processes to manage safety incidents well and learned lessons from them.
- Managers monitored the effectiveness of the service and made sure staff were competent. Staff worked well together for the benefit of patients and had access to good information.
- The service planned and provided care in a way that met the needs of local people and local organisations to plan care. People could access the service when they needed it. Reporting times exceed national standard.
- Staff understood the service's vision and values, and how to apply them in their work. Staff felt respected, supported and valued. Staff were clear about their roles and accountability. The service engaged well with their referring organisations and all staff were committed to improving services continually.

However:

- The provider had not carried out VDU risk assessments, there were no formal recordings that monitors met the Royal College of Radiologists (RCR) recommendations.
- There was no quality assurance programme to ensure monitors were calibrated and quality parameters assessed.
- Policies and procedures did not always reference appropriate national guidance to ensure they were in line with current legislation, standards and evidence-based guidance.
- The staffing matrix to record consultant radiologists' appraisals, revalidation, mandatory training and medical indemnity insurance was not up to date.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic and screening services	Good 	

Summary of findings

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Summary of this inspection

Background to Heart & Lung Imaging Limited

Heart and Lung Imaging Limited provide teleradiology services reviewing low radiation dose computed tomography (CT) images. The provider reports on behalf of the NHS trusts, private healthcare providers academia and industry partners. The provider mainly reports for the targeted lung health check programme (TLHC). The pilots focused on people aged 55 – 74 years of age. The provider is a remote cloud-based organisation and does not see patients face to face.

Teleradiology is the transmission of images and associated data between locations for the purpose of primary interpretation or consultation and clinical review. The service has no direct contact with patients and does not provide direct patient care. The service reported on adults only.

At the time of the inspection there was a registered manager in place. The nominated individual was also the registered manager.

The service is registered to carry out the following regulated activities: Diagnostic and screening procedures.

The service has not been inspected since its registration on 8 January 2021 and this was the first time the service had been inspected and rated.

How we carried out this inspection

We inspected this service using our comprehensive inspection methodology. We carried out the unannounced part of the inspection on the 21 July 2022.

Following the inspection, on the 25, 26, 27, 28 and 29 July, we conducted telephone interviews with the medical director and IT lead, quality assurance and research lead and governance lead and two radiologists.

The inspection team comprised of a lead CQC inspector and a CQC specialist advisor. The inspection team was overseen by Nicola Wise, Head of Hospital Inspection.

You can find information about how we carry out our inspections on our website: <https://www.cqc.org.uk/what-we-do/how-we-do-our-job/what-we-do-inspection>.

Outstanding practice

We found the following outstanding practice:

- The provider reported that 100% of scans were reported within 72 hours which is within in the NHS England guidance of 120 hrs.
- The provider had designed and implemented RYG (red, yellow, green) alert system to help local staff triage and action reports effectively.

Summary of this inspection

Areas for improvement

Action the service **MUST** take is necessary to comply with its legal obligations. Action a service **SHOULD** take is because it was not doing something required by a regulation but it would be disproportionate to find a breach of the regulation overall, to prevent it failing to comply with legal requirements in future, or to improve services.

Action the service **MUST take to improve:**

- The service must ensure policies and procedures reference appropriate national guidance.
- The service must ensure the relevant recruitment and ongoing compliance checks are kept up to date.
- The service must undertake visual display unit (VDU) risk assessments and have a record to confirm monitors meet the Royal College of Radiologists (RCR) recommendations.

Action the service **SHOULD take to improve:**

- The service should ensure a quality assurance programme is in place to ensure monitors are calibrated and quality parameters assessed.

Our findings





Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic and screening services	Good	Inspected but not rated	Not inspected	Good	Requires Improvement	Good
Overall	Good	Inspected but not rated	Not inspected	Good	Requires Improvement	Good

Diagnostic and screening services

Good 

Safe	Good 
Effective	Inspected but not rated 
Responsive	Good 
Well-led	Requires Improvement 

Are Diagnostic and screening services safe?

Good 

This is the first time we have rated safe. We rated it as good.

Mandatory training

The service did not provide mandatory training in key skills to staff but ensured it had been completed in the staffs substantive NHS roles.

The service did not provide mandatory training for its staff. We saw evidence that all staff completed mandatory training in their posts within the NHS. The mandatory training required was safeguarding adults' level 2, equality and diversity and Information governance.

All reporting cardiothoracic radiologists were employed as independent contractors and completed their mandatory training in their substantive posts within the NHS. Evidence of training was provided as part of the services onboarding process. This information was included on the compliance tracker and was monitored.

Safeguarding

Staff understood how to protect patients from abuse and had training on how to recognise and report abuse and they knew how to apply it.

Staff knew how to identify adults at risk of, or suffering, significant harm and worked with other agencies to protect them. The service had an up to date safeguarding adult policy. Staff knew who to inform if they had concerns and could access support from the host NHS trust and Heart and Lung Limited safeguarding lead if needed. Radiology staff also had access to the NHS safeguarding app.

All reporting radiologists and senior staff were required to complete safeguarding adults, level two training, in line with the Royal College of Nursing (RCN) intercollegiate document on safeguarding. The service provided evidence that radiologists and staff completed safeguarding training in their substantive posts within the NHS.

Relevant recruitment checks were completed for all staff and contractors. These included a disclosure and barring service (DBS) check and professional registration checks.

Cleanliness, infection control and hygiene

Not applicable as the service did not have any direct face to face contact with patients

Diagnostic and screening services

Environment and equipment

The service could not be fully assured that equipment was suitable for the reporting of imaging services.

The service checked that staff and radiologists had suitable equipment to work remotely from home. Staff told us as part of the induction process the adequacy of the IT equipment and screen quality was checked to ensure equipment complied with *Royal College of Radiologists* (RCR) guidance: picture archiving and communication systems (PACS) and guidelines on diagnostic display devices, third edition, though this was not formally recorded.

The provider did not have in place a system for staff and radiologists did not undertake risk assessments for the use of visual display units (VDU's). The provider advised they will undertake VDU risk assessments going forward.

The service did not have a process for ensuring that monitors were calibrated, and quality parameters assessed using a quality assurance programme. Two reporting radiologists we spoke with told us the equipment they used had been provided by their NHS trust for home working and quality assurance was undertaken by their trusts.

Assessing and responding to patient risk

Staff identified and quickly acted upon risks identified when reviewing patient scans.

The service only reported on the targeted lung health check (TLHC) programme. Reporting was undertaken by consultant radiologists with recognised expertise in cardiac and or thoracic radiology.

The provider had developed a clinical alerts system which was RYG (red, yellow, green) rated which followed the Royal College of Radiologist (RCR) and NHS England standard protocol for the programme. All scans are initially read using AI (artificial intelligence) technology which generated a standardised report template with a free text box so radiologists could add further comments. Reports were returned to the appropriate referring organisation via nominated email addresses. Feedback from trusts commented on the concise nature of reports which aided communication in multi-disciplinary team meetings (MDT).

Urgent findings that required immediate clinical action where flagged using a critical alert. The reporting radiologist would telephone the onsite hospital co-ordinator, surgical or medical specialist registrar depending on the site's standard operating procedure (SOP) so they could be followed up immediately. The leadership team advised there had been seven critical alerts raised since they started operating.

Referring organisations were able to contact members of the leadership team to discuss any report of findings. Members of the leadership team could also be contacted by radiologist performing scans on mobile scanners if they found suspicious areas or pathologies so they could report the scans immediately.

A reporting radiologist told us they had identified one site which was not scanning patients at the correct intervals which meant patients were not being scanned within the right time frames. This was raised with the leadership team who followed this up with the trust.

The service did not have any direct face to face contact with patients and only provided the diagnostic reports of patients' images which was part of the medical pathway for the patients.

Staffing

The service had enough staff with the right qualifications, skills, training and experience to keep patients safe from avoidable harm and to provide the right care and treatment.

Diagnostic and screening services

The service focused on the targeted lung health check (TLHC) low dose CT chest scans for lung cancer screening.

The provider employed two part time staff, the provider advised their function and roles were like their current NHS posts. All the radiologists were specialists in reporting cardiothoracic radiology and worked as contractors alongside their NHS role. As part of their contract, radiologists were not allowed to work during NHS rostered hours, working hours or for another provider. At the time of the inspection, the service had 50 consultant thoracic radiologists who worked as contractors, however only 74% (37) had provided evidence of current medical indemnity insurance.

Computed Tomography (CT) reporting workflow was co-ordinated by the service. Radiologists were emailed twice a week and allocated work depending on their availability. The service used a secure cloud-based radiology platform so radiologists could access images at any time. The provider advised they had the radiology capacity to meet the demands of reporting within service level agreement timescales.

Records

Staff kept detailed records of patients' diagnostic assessment. Records were clear, up to date, stored securely and easily available to staff.

The provider used a secure cloud-based medical image management suite which allowed for the rapid and efficient exchange of imaging among care providers. This allowed reporting radiologists easy and immediate access to data where and when needed. Reporting radiologists used a remote two factor authentication login system to access patient information and could only report on images assigned to them which assured security and confidentiality.

The provider with their software provider had developed a system using the NHS number as the unique primary identifier. This allowed them to access previous scans taken at different locations.

Reporting was done in a standardise format following RCR guidelines.

The provider had an up to date information governance policy and provided evidence that consultant radiologists and staff completed information governance training in their substantive posts within the NHS.

Medicines

The service used systems and processes to safely prescribe, administer, record and store medicines.

Not applicable as the service did not have any direct face to face contact with patients

Incidents

The service managed patient safety incidents well. Staff recognised incidents and near misses and reported them appropriately.

There was a policy and process in place for reporting, investigating and learning from incidents. Staff and reporting radiologists, we spoke with knew what incidents to report and how to report them. The service reported they had no incidents.

The provider had a duty of candour policy which staff could access. Radiologists we spoke with were aware of their responsibilities under the duty of candour. The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of

Diagnostic and screening services

certain notifiable safety incidents and provide reasonable support to that person, under Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. A notifiable safety incident includes any incident that could result in, or appears to have resulted in, the death of the person using the service or severe, moderate or prolonged psychological harm.

Are Diagnostic and screening services effective?

Inspected but not rated 

Evidence-based care and treatment

The service provided care and treatment based on national guidance and evidence-based practice.

All scans were reported in line with best practice and national guidance as set out by the Royal College of Radiologist (RCR) and NHS England such as the standard protocol for targeted screening for lung cancer with low radiation dose computed tomography and the quality assurance standards for targeted screening for lung cancer with radiation dose computed tomography.

The provider also had a system in place to review and update its policies and procedures. We reviewed a sample of the policies and found some did not reference appropriate national guidance to ensure they were in line with current legislation, standards and evidence-based guidance.

All staff, including reporting radiologists, had remote access to the service's policies and protocols. This meant all staff had access to the policies and procedures at all times.

Nutrition and hydration

Not applicable as the service did not have any direct face to face contact with patients

Pain relief

Not applicable as the service did not have any direct face to face contact with patients

Patient outcomes

Managers monitored the effectiveness of reporting and used the findings to improve the service.

The provider had a robust audit system in place to regularly assess and monitor the quality of the reporting, ensuring patient outcomes were monitored.

The service provided audit data to responsible clinicians at referring sites for the NHS England lung cancer screening pilot quarterly as outlined in NHS England guidance for screening pilots. This included the lung nodule recall rates, actionable incidental rates and quality assurance findings from 10% double reading of images. Referring sites also had feedback on the percentage referral rate for red and yellow findings.

The service undertook routine peer reviews for each radiologist on a quarterly basis, with 10% of their reports randomly audited. The service was able to statistically analyse referral rates of reports for red and yellow alerts, this was anonymised, but each reporter knew who they were and could see their performance relative to other reporters and if

Diagnostic and screening services

they were within the threshold of 10 -14% for referral of incidentals. If a reporter was above the 10 -14% threshold, this would be followed up individually. This ensured that discrepancies and learning opportunities were identified. Reporting radiologists we spoke with advised this information gave them a benchmark for their practise and was not available to them in the NHS. They felt this helped to improve the standards of reporting.

The provider undertook two Radiology Events and Learning Meetings (REALMS) per year, these were undertaken virtually. Minutes of these meetings demonstrated that radiological discrepancies were anonymously reviewed alongside good spots. The cases and learning were shared after each meeting for those radiologists who were not able to attend.

The providers had an up to date quality management policy.

Competent staff

The service made sure staff were competent for their roles.

The provider had an induction policy. All consultant radiology staff had a full induction and had to confirm eligibility for lung cancer screening which included reporting more than 500 CT scans a year, regular attendance of lung multi-disciplinary meetings and had to undertake the British Society of Thoracic Imaging (BSTI) nodule training.

Radiologist staff we spoke with confirmed their induction was undertaken on a one to one basis, and as part of the induction process, a senior manager reported two cases with them, a further eight test cases were double read and the first ten reports produced independently were double read and signed off to ensure accuracy in reporting before being sent to the referring trust. This met the RCR quality assurance standards for targeted screening for lung cancer with radiation dose computed tomography.

Consultant radiologists worked as contractors and were required to provide evidence of appraisals, revalidation and General Medical Council (GMC) professional registration. Data provided showed 72% of radiologists had provided evidence of an up to date appraisal in the last 12 months. The provider advised they provided radiologist fitness to practise statements which fed back into their NHS trust appraisal process.

Multidisciplinary working

Staff worked together as a team to benefit patients. They supported each other to provide good care.

Radiology staff provided prompt reporting, using a RYG (red, yellow, green) clinical alert system to triage computed tomography (CT) scans for the referring trusts to support local MDT meetings. Reports identified as red or yellow would be taken to an MDT meeting. We saw evidence from trusts which commented that the provider was also available to discuss scans in detail with the clinicians.

We saw evidence the service received feedback from local radiologists who also worked for the provider following MDT discussions. The provider advised this was encouraged as no formal process was currently in place.

The provider used a secure messaging service, which the reporting radiologist could use to share findings and ask questions. Radiologists we spoke with were very positive about using this format as it brought together a cohort of specialist radiologist which encouraged learning and improved patient care.

Seven-day services

Key services were available to support timely patient care.

Diagnostic and screening services

The service had no defined hours of operation as staff and the reporting radiologists worked remotely outside their NHS hours. Radiologists were available to report 7 days per week.

Health promotion

Not applicable as the service did not have any direct face to face contact with patients

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

Not applicable as the service did not have any direct face to face contact with patients

Are Diagnostic and screening services responsive?

Good 

This is the first time we have rated responsive. We rated it as good.

Service delivery to meet the needs of local people

The service planned and provided care in a way that met the needs of local people and local organisations to plan care.

The service was delivered flexibly by radiologists working outside of normal NHS job plan hours. All work was allocated depending on radiologist availability. The service met the needs of referring NHS trusts and NHS England lung screening sites by meeting the agreed key performance indicators (KPI's).

The provider provided imaging services to NHS trusts and clinical commission groups (CCG's), who were delivering part of the Targeted Lung Health Checks (TLHC) programme overseen by NHS England as part of the NHS plan to improve early diagnosis and survival for those diagnosed with cancer.

Meeting people's individual needs

Not applicable as the service did not have any direct face to face contact with patients

Access and flow

People could access the service when they needed it and received the right care promptly. Reporting times exceed national standards.

The service reported on a total of 40,579 scans in the twelve month period July 2021 to June 2022.

Senior managers monitored reporting times to ensure they were in line with SLA's and contracts. The provider reported that 100% of scans were reported within 72 hours which is within the NHS England guidance of 120 hrs.

Feedback from NHS trusts all commented on the prompt reporting turnaround times. One trust commented the provider had started reporting for them in January 2021 to tackle the backlog in TLCH screening created after the Covid19 pandemic programme with excellent results and had renewed their contract with Heart and Lung Imaging Limited for the next part of the screening programme.

Diagnostic and screening services

The provider is a remote cloud-based organisation. Their business continuity plan set out timescales and actions to be taken if there was any disruption to the service.

Learning from complaints and concerns

The service treated concerns and complaints seriously, investigated them and shared lessons learned with all staff.

The provider's quality management policy included a process for managing complaints. This included a dedicated email address for complaints, timescales for acknowledging receipt of complaints and timescale to investigate and resolve any complaint.

The provider reported there has been no complaints received since the service started to operate. The policy set out that were to be reviewed as part of quarterly governance meetings which would be attended by the senior leadership team.

Are Diagnostic and screening services well-led?

Requires Improvement 

This is the first time we have rated well-led. We rated it as requires improvement.

Leadership

Leaders had the skills and abilities to run the service. They understood and managed the priorities the service faced. They were visible and approachable to all staff.

There was a clear leadership structure. A chief executive officer (CEO), who was also the registered manager, had overall accountability for the service and was supported by senior leadership team members, which included the medical director and IT lead, quality assurance and research lead, and governance lead. The leaders had the skills, knowledge and experience they needed for their roles.

The senior leadership team were motivated to provide a high-quality service and there was a strong emphasis on working collaboratively and as a team.

Consultants told us they had good working relationships with the senior leadership team, they described them as being easily accessible, approachable and very supportive.

Vision and Strategy

The service had a vision for what it wanted to achieve and a strategy to turn it into action, developed with all relevant stakeholders. The vision and strategy aligned to local plans within the wider health economy. Leaders knew how to apply them and monitor progress.

The provider had a clear vision for the service. The provider's core objectives included 'to deliver the highest quality cardiothoracic radiology diagnostic expertise, 'wherever the patient'. The service's strategy was to 'deliver innovative and flexible solutions for cardiothoracic radiology reporting' which were 'value for money and financially sustainable'.

Diagnostic and screening services

The service focused on providing services to NHS providers who were delivering the targeted lung health check (TLHC) pilots with the objective of providing evidence for the need of a national programme. All the staff we spoke with were passionate about doing things right and particularly about picking up early cancers, they were motivated and aware of their contribution in achieving this.

Culture

Managers promoted a positive culture that supported and valued staff, creating a sense of common purpose based on shared values. The service had an open culture where staff could raise concerns without fear.

The radiologists we spoke with praised the leaders and the service that was being provided. Staff were encouraged and felt able to raise and report concerns and incidents. Learning was shared through Radiology Events and Learning Meetings (REALM) and 10% of each radiologists' reports were double read.

Staff told us there was good teamworking and were committed to delivering a good service. Staff were enthusiastic about the service they provided for patients. There were opportunities for further learning and development. The provider contributed to radiologists' annual NHS appraisal by providing fitness to practise reports.

The leadership team were aware of their responsibilities under duty of candour and had systems in place to ensure compliance.

Governance

Leaders mostly operated effective governance processes. Radiologists were clear about their roles and accountabilities and had regular opportunities to meet, discuss and learn from the performance of the service.

The leadership team advised they would address any issues as they arose and had not yet scheduled any formal governance meetings.

REALM meetings and the quality assurance process for reporting provided clinical oversight to identify issues, radiologist reporting outside the threshold of 10 -14% for referral of incidentals.

The provider had regular meetings with partner organisations to monitor the service level agreements. Minutes of one of these meetings demonstrated the key performance indicators were reviewed.

The service had systems in place to monitor radiologists General Medical Council (GMC) qualification, training, appraisals, indemnity insurance and revalidation. However, this was not up to date. The provider was 80% compliant with all requirements. The doctors Responsible Officer roles were undertaken by the radiologist's home NHS trusts. All staff were subject to Disclosure and Barring (DBS) checks.

Radiologists we spoke with were clear about their roles and who they were accountable to and felt the leadership team had effective oversight of the service.

Management of risk, issues and performance

Leaders and teams used systems to manage performance effectively. They identified and escalated relevant risks and issues. They had plans to cope with unexpected events.

Diagnostic and screening services

There was a programme of clinical and internal audit to monitor performance and manage risk. The provider randomly audited 10% of each reporting radiologists' reports on a quarterly basis and provided them with quality assurance reporting on a quarterly basis, which measured their reporting of red and yellow alerts relative to other reporters. REALM meetings were used to share learning.

All scans were reported in line national guidance and best practice and as set out by the Royal College of Radiologist (RCR) and NHS England.

The provider had a risk register which identified 5 risks, which were reviewed regularly. Each risk had a plan to mitigate the consequences of the risks including contingency plans for IT failure.

The provider had an up to date business continuity plan which set out the steps and timescales for business to return to normal.

Information Management

The service collected reliable data and analysed it. Reporting radiologist could find the data they needed, in easily accessible formats, to understand performance to make decisions and improvements. The information systems were integrated and secure. Data or notifications were consistently submitted to external organisations as required.

The provider's performance was monitored through their SLA's and contracts. Audit data was provided for the NHS England lung cancer screening pilot so referring sites could report quarterly. The provider advised they also provided feedback to NHS England on lessons learnt from the data.

The provider's data protection is provided by a third-party firm, which had produced a data protection report. This demonstrated compliance with General Data Protection Regulations (GDPR) since July 2020, which included a data protection policy, data breach and incident notification policy and data quality policy.

The provider had completed the annual self-assessment standard for 2021/2022 for the Data Security and Protection Toolkit which meant the provider had met the data guardians 10 data security standards.

The provider had remote IT support available 24 hours a day 7 days per week provided by their software providers.

The provider had up to date cyber insurance in place.

Staff had secure access to the service's intranet, which gave them access to a range of policies, procedures and guidance and their training and personal development records.

The provider was registered with the Information Commissioners Office (ICO). The service reported there had been no data breaches. The service had an up to date information governance policy.

Engagement

The provider engaged well with staff, reporting radiologists' staff and referring organisations to plan and manage services. They collaborated with partner organisations to help improve services for patients.

The provider used a range of methods (email, phone and secure messaging) to ensure staff and reporting radiologists were kept up to date.

Diagnostic and screening services

Reporting radiologists were positive about the leadership team describing the support as 'excellent' and 'faultless'. They felt comfortable about raising any concerns.

The provider advised that, following feedback from reporting radiologists, 'good spots' had been included as part of REALM meetings for discussion and learning. Additional recruitment was also in process at the time of inspection following feedback by a staff member to increase the PACS and IT support for the service.

The provider had regular meetings with referring organisations to monitor their performance. Feedback from referring organisations rated their performance as excellent in all four areas assessed. One provider commented they 'are keen to work as part of a team to ensure the service is delivered to a very high standard and this is reciprocated'. Another said, 'the working relation with Heart and Lung Ltd has been transparent and trustworthy'.

The provider had an up to date whistleblowing policy.

Learning, continuous improvement and innovation

All staff were committed to continually learning and improving services. They had a good understanding of quality improvement methods and the skills to use them. Leaders encouraged innovation and participation in research.

The leadership team was focused on continuous improvement to improve reporting. The provider had created a reporting manual for reporting radiologists for lung cancer screening reporting, as it was different to their routine NHS work.

The provider had designed and implemented RYG (red, yellow, green) alert system to help local staff triage and action reports effectively. The provider had registered this in the UK and European for Instructional Chart design.

The provider was working with their software provider to develop the NHS number of the as unique primary identifier, to build an infra structure which allowed for the linking of patient scans from different trusts.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

The table below shows the legal requirements that were not being met. The provider must send CQC a report that says what action they are going to take to meet these requirements.

Regulated activity	Regulation
Diagnostic and screening procedures	<p>Regulation 17 HSCA (RA) Regulations 2014 Good governance</p> <ul style="list-style-type: none">• The provider had not carried out VDU risk assessments, there were no formal recordings that monitors met the Royal College of Radiologists (RCR) recommendations.• Policies and procedures did not reference appropriate national guidance to ensure they were in line with current legislation, standards and evidence-based guidance.• The staffing matrix to record consultant radiologists' appraisals, revalidation, mandatory training and medical indemnity insurance was not up to date.