Brayford Studio Limited

Brayford Studio Limited

Inspection report

DUNCAN & TOPLIS
5 Resolution Close
Boston
PE21 7TT
Tel: 01522683347
www.4dscanning.co.uk

Date of inspection visit: 18 September 2023
Date of publication: 24/11/2023

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	Inspected but not rated
Are services safe?	**Inspected but not rated**
Are services effective?	**Inspected but not rated**
Are services well-led?	**Inspected but not rated**

Summary of findings

Overall summary

Brayford Studio is an independent ultrasound clinic based in Lincoln, providing scanning services to self-funding patients.

We carried out a short notice announced focused inspection to follow up concerns we found at our last inspection in July 2023 where we rated the diagnostic and screening core service as inadequate overall.

We only inspected some of the key questions of safe and well led as this is where the breaches of regulations were found.

We did not inspect the safe, effective and well led key questions in full, instead, we focused on the key lines of enquiry where serious concerns had been previously identified to see if improvement had been made.

We did not re-rate the service as we only looked at areas based around the breaches. We inspected the service to determine if the service had made improvements.

We found that:

- Staff did not provide safe care at all times. The service did not have accurate and complete care records and patients' paper records were not stored securely. The ultrasound machine containing patient information was not password protected. The process for the destruction of records was not clearly set out within legal guidelines. Quality assurance checks of equipment were not recorded. The service did not control infection risk well, the cleaning of equipment had not been recorded, and cleaning products were not fit for purpose. An infection control audit carried out did not support the identification of all relevant risks.
- The effectiveness of the service had not been monitored. Audits to monitor patient outcomes were not carried out in line with the service's clinical governance policy. There was no benchmarking or review of the quality of scans.
- Managers did not operate effective governance processes. We found insufficient evidence of assessment of the quality and safety and effective monitoring the performance of the service. The service lacked processes to identify and manage risk. The service did not seek feedback from patients and there was limited continuous improvement and learning activities.

However, we found that:

- Staff had completed training modules including safeguarding children and adults' level 3, information governance and general data protection regulation, mental capacity act, learning disability and autism awareness.
- Control of substances hazardous to health (COSHH) risk assessments and product data sheets were available within the service.
- A 5 year fixed wiring assessment had been carried out and a certificate of satisfaction available.
- Portable appliance testing had been completed.
- The manager provided evidence of medical indemnity insurance.

Summary of findings

Our judgements about each of the main services

Service		Rating	Summary of each main service
Diagnostic and screening services	**Inspected but not rated**		See summary above

Summary of findings

Contents

Summary of this inspection

Page

Background to Brayford Studio Limited 5

Information about Brayford Studio Limited 6

Our findings from this inspection

Overview of ratings 8

Our findings by main service 9

Summary of this inspection

Background to Brayford Studio Limited

Brayford Studio Limited is an independent ultrasound service based in Lincoln. The service offers a range of obstetric and gynaecology ultrasound scans providing both medical and diagnostic scans, 4D bonding and pregnancy reassurance scans. People generally self-refer to this service. Brayford Studio Limited has a registered manager who is also the owner and the only sonographer, they are also a GMC registered gynaecologist. At the time of our inspection there were no other staff employed at the service.

The service has been registered with CQC to carry out the regulated activity of Diagnostic and Screening procedures since 6 April 2022.

At our previous inspection we found the following breaches of regulation:

- The service must ensure, where patients are required to provide relevant information on consent forms about medical information, in order to identify risks to the individual patient, that this is complete. (Regulation 12, safe care and treatment).
- The service must ensure disposable equipment is in date and fit for use. (Regulation 12, safe care and treatment).
- The service must ensure that environmental cleaning records and audits are completed and that surfaces are free from dust. (Regulation 12, safe care and treatment).
- The service must ensure there is a clear protocol and record of decontamination of the ultrasound transducer and equipment used for decontamination is fit for purpose. Transducer sheaths must be in line with manufacturer recommendations and within the expiry date to minimise the risk of infection. (Regulation 12, safe care and treatment).
- The service must ensure sharps bins for the storage of used needles and sharp instruments are disposed of in line with National Institute for Health and Care Excellence best practice guidelines (2012) Healthcare-associated infections: prevention and control in primary and community care. (Regulation 12, safe care and treatment).
- The service must ensure maintenance of equipment is carried out in line with the manufacturer's recommendations, ensuring that scanning machines are fit for purpose. (Regulation 15, premises and equipment).
- The service must ensure environmental safety and fire safety maintenance are carried out in accordance with the recommendations of risk assessments and that risk assessments are carried out annually. (Regulation 15, premises and equipment).
- The service must ensure that control of substances hazardous to health (COSHH) data sheets and risk assessments are held on the premises. (Regulation 15, premises and equipment).
- The provider must ensure there is information on how to complain shared with people who use the service and visible within the service. (Regulation 16, receiving and acting on complaints).
- The service must ensure service user records are stored securely. (Regulation 17, good governance).
- The service must ensure records are complete, legible, dated, signed and must include clearly identifiable information of the service user such as full name and date of birth. (Regulation 17, good governance).
- The service must ensure there is a clear policy for the retention and destruction of records. (Regulation 17, good governance).
- The registered person must ensure the service has full medical indemnity insurance. (Regulation 17, good governance).
- The service must ensure training updates are completed. (Regulation 17, good governance).
- The service must ensure it actively seeks service user feedback to evaluate and improve the quality of the service provided. (Regulation 17, good governance).

Summary of this inspection

- The service must ensure there are regular quality assurance and improvement audits and reviews of the quality of treatment and care provided by the service in line with the service's clinical governance policy. (Regulation 17, good governance).
- The provider must ensure any staff employed by the service have full checks and reviews in line with employment law and statutory requirements, and a record of their employment is maintained. (Regulation 19, fit and proper persons employed).

How we carried out this inspection

We completed an onsite visit to the service on 18 September 2023. The inspection team consisted of 2 CQC inspectors and a specialist advisor in sonography.

On the day of inspection, there were no services running due to action taken by CQC to suspend the providers registration because of the breaches to regulation.

Our inspection was announced with short notice. We gave the registered manager notice of the inspection date to ensure their availability on the day.

During the inspection we interviewed the registered manager/sonographer (who was the only employee of the service), reviewed scan and consent records, policies and procedures, and training records. We reviewed 6 scan and consent records. We did not observe scanning procedures as there were no scans booked in at the time of our 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.

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 that infection prevention and control audits are completed in such a way that they identify risks and areas for improvement, and that surfaces are free from dust. (Regulation 12, safe care and treatment).
- The service must ensure there is a clear protocol and record of decontamination of the ultrasound transducer and equipment used for decontamination is fit for purpose. Transducer sheaths must be in line with manufacturer recommendations and within the expiry date to minimise the risk of infection. (Regulation 12, safe care and treatment).
- The service must ensure sharps bins for the storage of used needles and sharp instruments are disposed of in line with National Institute for Health and Care Excellence best practice guidelines (2012) Healthcare-associated infections: prevention and control in primary and community care. (Regulation 12, safe care and treatment).
- The service must ensure quality assurance testing of equipment is carried out in line with the manufacturer's recommendations, ensuring that scanning machines are fit for purpose. (Regulation 15, premises and equipment).

Summary of this inspection

- The service must ensure environmental safety and fire safety maintenance checks are embedded within the service. They must ensure that all risks are identified, and action taken to mitigate them. (Regulation 15, premises and equipment).
- The service must ensure service user records are stored securely. (Regulation 17, good governance).
- The service must ensure records are complete, legible, dated, signed and must include clearly identifiable information of the service user, scan findings and recommendations. (Regulation 17, good governance).
- The service must ensure there is a clear policy for the retention and destruction of records, including how destruction will be carried out in line with information governance and safety requirements. (Regulation 17, good governance).
- The service must ensure it actively seeks service user feedback to evaluate and improve the quality of the service provided. (Regulation 17, good governance).
- The service must ensure there are regular quality assurance and improvement audits and reviews of the quality of treatment and care provided by the service in line with the service's clinical governance policy. (Regulation 17, good governance).
- The provider must ensure any staff employed by the service have full checks and reviews in line with employment law and statutory requirements, and a record of their employment is maintained. (Regulation 19, fit and proper persons employed).

Our findings

Overview of ratings

Our ratings for this location are:

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

Inspected but not rated

Diagnostic and screening services

Safe	Inspected but not rated
Effective	Inspected but not rated
Well-led	Inspected but not rated

Is the service safe?

Inspected but not rated

Mandatory training

At the July 2023 inspection we identified gaps in the completion of mandatory training. At this inspection we found that some updates had been completed, including updates in safeguarding children and vulnerable adults at level 3. At the time of the inspection, training updates had yet to be completed in relation to the Mental Capacity Act (2005), information governance, general data protection regulations (GDPR), learning disability and autism awareness. However, the registered manager provided evidence of training completion in these areas following the inspection.

Cleanliness, infection control and hygiene

The service did not control infection risk well. The manager did not use equipment and control measures to protect patients, themselves and others from infection.

At the July 2023 inspection we identified concerns in relation to cleanliness, infection control and hygiene. At this inspection we found clinical areas were mostly clean and had suitable furnishings which were clean and well-maintained. However, we saw clutter on the base plate of the ultrasound machine and there was visible dust.

Cleaning records showed that the general environment had been regularly cleaned. However, there were no records of cleaning of the ultrasound transducer and the manager did not have a process in place to record this. Therefore, they could not evidence that regular cleaning had been carried out. Cleaning wipes were not manufacturer recommended in line with British Medical Ultrasound Society (BMUS) decontamination guidance. Although, alcohol based wipes were available, the manager was unaware of the risks of the use of alcohol in relation to the potential degradation to the ultrasound probes.

The manager followed some infection control principles, including the use of personal protective equipment (PPE). We saw that gloves and aprons were available on the premises. However, we also found items of PPE and paper towels discarded in drawers and a cupboard within the clinic.

An infection prevention and control audit had been carried out the day before our inspection. The audit had failed to identify all infection control risks within the clinic. For example, the clutter and dust seen on the ultrasound machine.

At this inspection we found that ultrasound gel was decanted from a 5 litre bottle that was in date, into a reusable gel container that was not dated. This was not in line with a November 2021 MHRA alert about the risk of infection with the use of reusable gel containers. where it was recommended that only pre-filled disposable containers of ultrasound gel be used and that providers cease using large containers intended for decanting.

At the July 2023 inspection the service did not have up to date safety data sheets and risk assessments for the use and storage of cleaning materials in line with Control of Substances Hazardous to Health (COSHH) regulations. At this inspection we found the service had COSHH data sheets and risk assessments in place.

Environment and equipment

The design, maintenance and use of facilities, premises and equipment did not keep people safe. The service did not manage clinical waste in line with guidance.

At the July 2023 inspection we found the design and maintenance of the environment did not always follow national guidance or the service's policy, including actions relating to a fire risk assessment that had not been completed. At this inspection we found some actions had been carried out, this included a 5 yearly fixed wiring check, with a certificate of safety provided. Annual portable appliance testing had been carried out in the week before our inspection, having previously not been completed since 2020. The manager told us they had made arrangements to ensure this was carried out annually in the future.

The manager told us they carried out weekly tests of the fire alarm system. At our previous inspection they were unable to provide records to demonstrate this. At this inspection we saw that 1 test of the fire alarm system had been carried out in the week prior to our visit. The manager told us they had received a demonstration on how to test the alarm on this date from a fire safety specialist and had been given the appropriate equipment to carry out weekly testing themselves. However, this process was not yet embedded.

The ultrasound machine in use had been calibrated in June 2023. There were no records of equipment handover forms in place to hand over to the engineer or receive back from the engineer. There was no evidence of routine quality assurance tests done on the machine to monitor the reliability of results and to check for deterioration in performance of the ultrasound scanner. A second ultrasound machine that had previously been stored in the waiting area, with a maintenance sticker dated 2019 had been removed from the clinic.

Not all environmental risks had been mitigated. For example, the door to the scanning room was difficult to open from the inside. The manager told us that previously the door handle had come off. However, they had not taken action to repair the door and had not identified risks relating to potential entrapment within the scanning room.

Although the service had a clear process for the disposal of clinical waste staff did not follow it. We found PPE discarded in drawers and a cupboard. A sharps bin for the use of disposing of needles used to carry out non-invasive prenatal testing (NIPT) had been assembled but had no date or signature recorded on it which was not in line with national infection prevention and control guidance.

Assessing and responding to patient risk

The service did not complete risk assessments for each woman in order to remove or minimise risks and information that may inform a risk assessment process was not always recorded. The service's referral policy was not consistently followed.

At the July 2023 inspection we found the manager did not complete risk assessments for each patient on arrival. Patients completed a consent form on arrival which included questions about any issues with their pregnancy such as vaginal bleeding or pain. However, responses to these questions were not always fully completed. Sonographer notes were written in the margin of the consent form and were sometimes illegible. This meant that the assessment of risk for individual patients was unclear. At this inspection the manager told us they were intending to provide a typed written summary of assessments and findings for each scan undertaken. This was not in place at the time of inspection.

Inspected but not rated

Diagnostic and screening services

Staff did not always identify potential risks. At the July 2023 inspection we found there was a referral policy that stated if there were any potential abnormalities identified on the scan then the woman would be referred to their local hospital for a second opinion. If there was a concern for the health of the baby or the woman, they would be advised to seek emergency care at their local hospital. At this inspection we found ongoing concerns about how the provider identified and escalated potential risks to patients and the unborn baby. For example, we viewed the results of a scan where the measurements of the baby could indicate a potential abnormality. The images indicated that the measurements may not be accurate. However, the manager had not identified either a potential abnormality or inaccuracy in the scanning processes. They told us they had taken the measurements 4 times, however, there was only 1 recorded measurement within the record on the ultrasound machine. We could not be assured the process for identifying risks and taking action was not comprehensive, and that risks to patients and the foetus were not appropriately assessed.

Records

The service did not keep detailed records of patients' care and diagnostic procedures. Records were unclear and not stored securely.

At our previous inspection in July 2023, we found that patient notes were not comprehensive and were not stored securely. . Following the July 2023 inspection, the manager had taken action to store consent forms in a folder in a locked drawer of a filing cabinet. However, at this inspection we found 6 loose consent forms containing patient information in a tray in the reception area. In addition, we found 3 printed scan images with patient identifiable information discarded on the base plate of the scanning machine.

At the July 2023 inspection the manager told us they kept additional records on a computer at home, to write letters for patients to pass onto their GP or NHS clinician. At this inspection we found that where correspondence was given to the patients to pass onto their GP or other professionals involved in their care, this had been printed and were attached to the consent form as a record of the scan findings.

At the July 2023 inspection the manager told us they backed up electronic records using memory sticks. The memory sticks were not on site at the clinic and were unable to confirm if they were suitably encrypted and password protected. This issue remained during this inspection. In addition, we found there was no password protection of the ultrasound scanning machine records.

At this inspection we found there was no policy for the destruction of records. The manager could not clearly articulate how records would be destroyed or who would do it. The ultrasound scanner had records dating back to 2022 where the scanning images had been deleted, but the names and details of the patients were still visible. The manager was not able to demonstrate how records were deleted or why some patient information was retained when the images had been deleted. Following the inspection, the provider sent us a proposed policy for the management of records, stating that images on the ultrasound machine would be deleted after 6 months and that paper records would be retained for 3 years then destroyed by burning. However, the policy did not include whether this was to be done on site or elsewhere and who would be responsible for ensuring their secure destruction.

There were no monitoring processes for the quality or governance of records. A proposed policy for the management of records stated that 6 monthly records audits would be carried out and that an initial audit had been completed and learning identified. However, evidence of this was not provided.

Incidents

The service had no recorded safety incidents. There was a policy that included an incident reporting form and reference to the duty of candour.

At the July 2023 inspection we found the service had a significant incident and event policy, including a reporting form that contained prompts to identify causes of issues and learning from them. There had been no events recorded within the service.

At this inspection we found the service had no identified safety incidents. However, an incident relating to a potential scan abnormality identified by CQC at the July 2023 inspection, that had not resulted in an appropriate referral had not been identified by the provider as a safety incident. Following the inspection, the manager told us they had recorded this incident, however, they had not reviewed the scan to identify learning and had not sought a review or further information in order to identify risks or potential improvements to scanning or referral processes.

Is the service effective?

Inspected but not rated

Patient outcomes

The service did not monitor the effectiveness of care.

At the July 2023 inspection we found the service did not have a process for reviewing clinical outcomes. Although the clinical governance policy stated audits should be carried out, these had not been completed. Therefore, there was no assurance that the outcomes for patients were positive, consistent and met expectations, such as national standards.

At this inspection we found the provider had not carried out audits in line with their clinical governance policy. Therefore, there continued to be no assurance that outcomes for patients met expectations.

At the July 2023 inspection we found consent forms were not always complete and no evidence to demonstrate the manager reviewed the forms or asked for further details or clarification where the forms did not include relevant information. At this inspection there was limited assurance of improvements in relation to the process of obtaining consent and while the manager told us they intended to provide a typed written scan summary we did not see evidence of how this would be carried out.

At the July 2023 inspection there was no evidence of quality review or improvement in relation to outcomes, and information was not used to improve care and treatment. There was no process for benchmarking the service or the quality of the scans carried out. Peer review audits were not carried out. The manager did not monitor the re-scan rate.

At this inspection, the manager had limited plans in place to ensure the quality of scans carried out. They told us they had plans to audit the scans and other aspects of the service. However, they did not demonstrate the process they intended to follow. In addition, they had not undertaken retrospective audits or quality assurance processes on scans previously conducted at the clinic, despite concerns raised by as at the previous inspection.

Competent staff

The service did not make sure staff were competent for their roles.

At the July 2023 inspection we found there was no process of review of the scanning competency of the sonographer. During this inspection the manager told us they were intending to request support in reviewing competency through the British Medical Ultrasound Society. However, there were no specific arrangements in place for this.

Inspected but not rated

Diagnostic and screening services

At the July 2023 inspection the manager told us no other staff were working at the service at the time of our inspection. Although previously the service had employed staff member to undertake a single non-invasive prenatal test (NIPT) that had been carried out in the current year. However, they did not hold any current information about the clinician and had no service level agreement or appropriate checks in place.

At this inspection, because the service was not undertaking any regulated activities, there were no other staff working at the clinic. The provider told us they would be looking to employ someone to undertake NIPT procedures when the service was running again.

Multidisciplinary working

The manager had links to external professionals to provide appropriate care for patients. However, we saw that referrals were not always made appropriately.

At the July 2023 inspection we found the service had a referral policy which stated that patients were to be referred to their local hospital in the event of abnormalities or where a second opinion was required. The manager told us they had not referred any patients to their local hospital in the last year. We viewed the record of one woman where an abnormality was seen on the scan where no referral was made.

At this inspection we found the manager had not reviewed the referral policy and processes in order to identify any potential missed referral opportunities following our previous inspection. They had not reviewed the scan where an abnormality had been found and had not reflected on their practice to identify opportunities for learning. We reviewed the scan of another patient where there the baby's measurements could potentially give rise to concerns. Again the manager had not identified this potential risk or the need for referral.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

The service did not follow national guidance to gain patients' consent. The manager knew how to assess patients who lacked capacity to make their own decisions, however, training updates were not in date.

At the July 2023 inspection the manager understood how and when to assess whether a patient had the capacity to make decisions about their care. The registered manager and sonographer had completed training in the Mental Capacity Act (MCA) but the training had expired in April 2023. At this inspection we found that MCA training updates had yet to be completed. A week after the on site inspection the manager sent us evidence that they had subsequently completed the training.

Is the service well-led?

Inspected but not rated

Leadership

The manager did not clearly demonstrate they ran the service safely with good governance.

At the July 2023 inspection we found the manager did not demonstrate they recognised the risks associated with running the service. These included risks associated with being unable to demonstrate indemnity cover, insufficient equipment and premises maintenance and management of risk, a lack of governance and feedback processes, and limited processes for monitoring performance.

Inspected but not rated

Diagnostic and screening services

At this inspection we found that some action had been taken to address areas of good governance, albeit it limited. Following the inspection, the manager provided evidence of current medical indemnity cover and some actions had been taken to improve areas such as security of records. However, the manager had failed to address the ongoing risks relating to premises and equipment, infection control, risk management, governance and feedback processes and ongoing limited processes for monitoring performance.

Governance

The manager did not operate effective governance processes. There was insufficient evidence of assessment of the quality and safety and effective monitoring of the service.

At the July 2023 inspection there was not an effective governance system in place for the service. During this inspection, the governance system remained ineffective. Ongoing safety risks were present in relation to the use of equipment, health and safety risks, infection control and the security and management of records. In addition, there were limited processes for managing performance, for example, in relation to identifying learning and improvement or the use of audit in line with the provider policy to improve the service provided.

At the July 2023 inspection we found the provision of the service and what was offered was not clear. The service did not have a clear inclusion or exclusion criteria for access to the service. For example, the manager said they did not currently carry out diagnostic or gynaecological scans as detailed on the service's website. However, we saw records indicating that gynaecological scans were carried out by the service and the service's statement of purpose stated gynaecological scans were carried out. At this inspection, the manager shared with us an updated statement of purpose that included they would no longer be undertaking diagnostic or gynaecological scans.

Management of risk, issues and performance

The manager did not use systems to manage performance effectively. The service lacked processes to identify and manage risk on a continuous basis and actions to reduce the impact of risk were insufficient.

At the July 2023 inspection there were identifiable risks relating to the management of the premises and equipment. At this inspection these risks remained, This included a door that was faulty, presenting a risk of potential entrapment. Fire safety checks, although now in place had not been embedded. Infection control risks were still apparent and processes in place to identify and address these were insufficient.

At the July 2023 inspection we found the service did not have a process to ensure the scans were being conducted effectively. There was no process to audit any rescans for patients. There was evidence the manager had not followed their referral process to an early pregnancy unit when a possible abnormality was seen on a scan. At this inspection, these concerns remained. Learning from a previous concern about a lack of referral to an early pregnancy unit in response to a potential abnormality was not apparent. There were no processes in place to audit scans for quality and safety and no peer review process in place. There was limited recognition of risks associated with the lack of these processes.

Information Management

The service did not collect reliable data or analyse it. Data had not been collected in accessible formats, to understand performance, make decisions and improvements. Not all information was secure. Information provided on the services website was inaccurate.

At the July 2023 inspection we found the service did not have systems to collect data and use this to make decisions and improvements. Information about scans and patients using the service was not reliable or maintained in line with

information governance guidelines. At this inspection we found ongoing concerns about the security and reliability of patient records. Whilst the manager had taken action to store records more securely, this was inconsistent. In addition, action to improve the legibility of handwritten records had not been implemented. The manager told us they had plans in place to provide type written reports on all scans, however, they were unable to evidence this or provide information on the format they would use.

We found ongoing limitations in the use of information to understand performance. The clinical governance policy stated information from patients and clinical audit was used to measure performance. However, audits were not undertaken, and feedback was not actively sought.

There were ongoing concerns about a lack of security in relation to electronic records. For example, the ultrasound machine was not password protected and the manager was unable to evidence how they backed up records held electronically. The manager told us they stored correspondence about some patients on their computer at home.

Information on the service website continued to be out of date and did not reflect the services offered.

Engagement

The manager did not actively engage with patients to get their feedback.

At the July 2023 inspection we found the manager did not actively seek feedback from patients about the service they received. Their clinical governance policy described a service user group with an aim of using engagement with this group to improve the running of the service. However, the group was not in operation at the time of the inspection.

At this inspection, the manager provided us with examples of patient feedback, but they were 5 or more years old. They did not have a process for actively seeking feedback from patients in order to obtain a balanced view of patient's experience in order to identify areas for improvement.

Learning, continuous improvement and innovation

The manager was not able to demonstrate commitment to continually learning and improving the service.

There continued to be insufficient evidence to demonstrate a commitment to improve the service. Some action had been taken to address concerns from our previous inspection such as training and some aspects of health and safety. However, there were areas where improvement was not evident, including in relation to quality assurance, records management and security, infection prevention and control, reviewing clinical outcomes, management of risk, learning from incidents and there was limited information used to support the management of performance.

This section is primarily information for the provider

Enforcement actions

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	Regulation 12 CQC (Registration) Regulations 2009 Statement of purpose • Infection prevention and control audits were not completed in such a way that they identify risks and areas for improvement, and that surfaces are free from dust. • There was not a clear protocol and record of decontamination of the ultrasound transducer and equipment used for decontamination is fit for purpose. Transducer sheaths must be in line with manufacturer recommendations and within the expiry date to minimise the risk of infection. • Sharps bins for the storage of used needles and sharp instruments were not managed in line with National Institute for Health and Care Excellence best practice guidelines (2012) Healthcare-associated infections: prevention and control in primary and community care.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance • The service did not ensure service user records are stored securely. • The service did not ensure records are complete, legible, dated, signed and must include clearly identifiable information of the service user, scan findings and recommendations. • The service did not ensure there is a clear policy for the retention and destruction of records, including how destruction will be carried out in line with information governance and safety requirements.

Enforcement actions

- The service did not ensure it actively sought service user feedback to evaluate and improve the quality of the service provided.
- The service did not ensure there were regular quality assurance and improvement audits and reviews of the quality of treatment and care provided by the service in line with the service's clinical governance policy.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 19 HSCA (RA) Regulations 2014 Fit and proper persons employed • The provider did not ensure any staff employed by the service have full checks and reviews in line with employment law and statutory requirements, and a record of their employment is maintained.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 15 HSCA (RA) Regulations 2014 Premises and equipment • Quality assurance testing of equipment was not carried out in line with the manufacturer's recommendations, ensuring that scanning machines are fit for purpose. • Environmental safety and fire safety maintenance checks were not embedded within the service. Not all risks were identified, so that action was taken to mitigate them.