Ecospirito Ltd

Fastrack Scan

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	Inadequate
Are services safe?	Inadequate
Are services effective?	Inspected but not rated
Are services caring?	Insufficient evidence to rate
Are services well-led?	Inadequate

Summary of findings

Overall summary

Fastrack Scan is operated by Ecospirito Ltd. The service is mobile and provides dual energy x-ray absorptiometry (DEXA) scans from a 7.5 tonne mobile unit.

We inspected diagnostic imaging services, which is the only service provided.

We previously inspected this service following the outcome of our short-notice announced comprehensive inspection on 2 April 2019, where we made the decision to suspend the service. We formally notified the provider that their registration in respect of carrying out a regulated activity was suspended for eight weeks, under Section 31 of the Health and Social Care Act 2008. The notice of urgent suspension was given because we believed that a person or persons will or may be exposed to the risk of harm if we did not take this action. We inspected the service again on 29 May 2019 so that we could be assured that a person or persons will not be exposed to the risk of harm.

To get to the heart of patients' experiences of care and treatment, we ask the same five questions of all services: are they safe, effective, caring, responsive to people's needs, and well-led? Where we have a legal duty to do so we rate services' performance against each key question as outstanding, good, requires improvement or inadequate. During this inspection, we did not collect sufficient evidence to rate caring and responsive. We do not currently rate the effectiveness of diagnostic imaging services.

Throughout the inspection, we took account of what people told us and how the provider understood and complied with the Mental Capacity Act 2005.

Services we rate

We previously inspected this service on 2 April 2019 and rated the service as inadequate overall. During the focussed inspection on 29 May 2019, we found improvements had been made. However, we still had some significant concerns and therefore rated the service as inadequate. During this inspection, we did not collect sufficient evidence to rate caring and responsive. We do not currently rate the effectiveness of diagnostic imaging services.

We found areas of practice that were inadequate:

- Whilst there were plans in place for staff to complete mandatory training, staff had not completed mandatory training in key skills at the time of our inspection.
- There was no formal certification of training undertaken.
- There was no clear process for managing incidents. Incidents were not investigated and details of discussions about incidents were not recorded. There was no evidence that lessons were learned and discussed with the team. The incident policy did not include the process for recording, investigating and learning from incidents.
- There was no process in place to ensure staff were following up to date guidance. No audits were carried out by the provider and no peer reviews had been undertaken.
- The service did not monitor the effectiveness of care and treatment and was therefore unable to identify and act upon areas that required improvement.
- There was no documented evidence that staff were competent for their roles. Staff's work performance was not appraised. This meant that staff were not supported to be competent in their roles and the effectiveness of the service and the quality of scans were not monitored.

Summary of findings

- We could not be assured that staff understood their roles and responsibilities under the Mental Health Act 1983 and the Mental Capacity Act 2005. They had not received any training at the time of our inspection. The mental capacity policy was not in line with Mental Capacity Act 2005. However, risks associated with radiation was explained. This was an improvement since our previous inspection.
- Whilst the registered manager had the skills, knowledge, and experience to perform DEXA scans, they had not fully established suitable and effective policies and procedures to fulfil all of the requirements of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (Part 3). The service did not have managers with the right skills and abilities to run a service providing high-quality care.
- There was no vision for what the service wanted to achieve and workable plans to turn it into action.
- Whilst staff were friendly and welcoming, the culture was not focussed on safety and quality.
- There was a lack of governance arrangements in place. The limited arrangements that were in place were not adequate to ensure high standards of care and oversight could be maintained. Systems and processes had not been established or operated effectively to assess, monitor and improve the quality and safety of the services provided in the carrying on of the regulated activity.
- The provider was failing to comply with Regulation 17, (1) (2), Good governance, of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

However, we also found the following areas of improvement since our previous inspection in April 2019:

- Whilst staff had not completed training on how to recognise and report abuse at the time of our inspection, this had been planned. Staff demonstrated an understanding of how to protect patients from abuse. This was an improvement since our previous inspection.
- The service had some processes to control infection risk. Staff had an improved knowledge of how they could be compliant with best practice for hand hygiene, in accordance with national guidelines. There was now an infection prevention and control policy in place and plans to complete cleaning schedules that had been developed.
- The provider had suitable premises. There were handwashing facilities. Environmental risk assessments had been completed. Equipment had been serviced within the last 12 months.
- There were some arrangements in place to assess and manage risks to patients. Risks associated with radiation were displayed. Local rules were dated, displayed, and had been signed by all staff. They were reflective of current guidance. Staff had the appropriate training to manage deteriorating patients.
- DEXA scans and local rules were based on national guidelines and standards.
- Staff undertook scans for patients with compassion. Feedback from patients confirmed that staff treated them well and with kindness.
- Risks associated, whilst low, were communicated clearly to patients. This was an improvement since our last inspection.
- Leaders had a better awareness of the employment checks and training that were required, which was an improvement since our previous inspection.
- Systems had been developed to identify, reduce and eliminate risks, and to cope with both the expected and unexpected.
- We saw some evidence of learning from previous inspection findings, plans to ensure staff completed training and improvements in infection prevention and control.

Following this inspection, we issued the provider with a warning notice under Section 29 of the Health and Social Care Act 2008. The warning notice was issued because regulation 17 (Good governance) had been breached, and not all concerns identified at the previous inspection had been addressed. The warning notice letter sent to the provider included the concerns we identified during this inspection and how the provider was failing to comply with this regulation. The provider must be compliant with this regulation by 21 July 2019. The Chief Inspector of Hospitals has recommended that the provider remain in special measures.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	Inadequate 	Our rating of this service remained the same. We rated it as inadequate because: • Whilst there were plans in place for staff to complete mandatory training, staff had not completed mandatory training in key skills at the time of our inspection. • There was no formal certification of training undertaken. • There was no clear process for managing incidents. Incidents were not investigated and details of discussions about incidents were not recorded. There was no evidence that lessons were learned and discussed with the team. The incident policy did not include the process for recording, investigating and learning from incidents. • DEXA scans and local rules were based on national guidelines and standards. However, there was no process in place to ensure staff were following up to date guidance. No audits were carried out by the provider and no peer reviews had been undertaken. • The service did not monitor the effectiveness of care and treatment and was therefore unable to identify and act upon areas that required improvement. • There was no documented evidence that staff were competent for their roles. Staff's work performance was not appraised. This meant that staff were not supported to be competent in their roles and the effectiveness of the service and the quality of scans were not monitored. • We could not be assured that staff understood their roles and responsibilities under the Mental Health Act 1983 and the Mental Capacity Act 2005. They had not received any training at the time of our inspection. The mental capacity policy was not in line with Mental Capacity Act 2005. However, risks associated with radiation was explained. This was an improvement since our previous inspection. • Whilst the registered manager had the skills, knowledge, and experience to perform DEXA scans, they had not fully established suitable and effective

Summary of findings

policies and procedures to fulfil all of the requirements of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (Part 3). The service did not have managers with the right skills and abilities to run a service providing high-quality care.

- There was no vision for what the service wanted to achieve and workable plans to turn it into action.
- Whilst staff were friendly and welcoming, the culture was not focussed on safety and quality.
- There was a lack of governance arrangements in place. The limited arrangements that were in place were not adequate to ensure high standards of care and oversight could be maintained. Systems and processes had not been established or operated effectively to assess, monitor and improve the quality and safety of the services provided in the carrying on of the regulated activity.
- The provider was failing to comply with Regulation 17, (1) (2), Good governance, of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

However, we also found:

- Whilst staff had not completed training on how to recognise and report abuse at the time of our inspection, this had been planned. Staff demonstrated an understanding of how to protect patients from abuse. This was an improvement since our previous inspection.
- The service had some processes to control infection risk. Staff had an improved knowledge of how they could be compliant with best practice for hand hygiene, in accordance with national guidelines. There was now an infection prevention and control policy in place and plans to complete cleaning schedules that had been developed.
- The provider had suitable premises. There were handwashing facilities. Environmental risk assessments had been completed. Equipment had been serviced within the last 12 months.
- There were some arrangements in place to assess and manage risks to patients. Risks associated with radiation were displayed. Local rules were dated,

Summary of findings

displayed, and had been signed by all staff. They were reflective of current guidance. Staff had the appropriate training to manage deteriorating patients.

- Staff undertook scans for patients with compassion. Feedback from patients confirmed that staff treated them well and with kindness.
- Risks associated, whilst low, were communicated clearly to patients. This was an improvement since our last inspection.
- Leaders had a better awareness of the employment checks and training that were required, which was an improvement since our previous inspection.
- Systems had been developed to identify, reduce and eliminate risks, and to cope with both the expected and unexpected.
- We saw some evidence of learning from previous inspection findings, plans to ensure staff completed training and improvements in infection prevention and control.

Summary of findings

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Background to Fastrack Scan

Fastrack Scan is a mobile scanning service operated by Ecospirito Ltd. The service opened in 2009 but was not registered with the CQC until May 2018. It is a mobile scanning unit that provides dual-energy x-ray absorptiometry (DEXA) scans across England, mainly self-funded patients of 15 years and above, to measure bone mineral density. Facilities are contained within a seven and a half tonne lorry and include one DEXA scan room, and a seated waiting area.

The service registered with the CQC in May 2018 to undertake the following regulated activities:

- Diagnostic and screening procedures.

The service has had a registered manager in post since their registration with CQC

Patients can self-refer or they can be referred by a clinician. The service also offers private scans to sports teams. We did not inspect these services.

The service is contracted to deliver a DEXA scanning clinic from a number of independent healthcare locations across England. They travel to the independent hospitals and park the lorry carrying the DEXA scan in the car park, where they see patients. The provider told us they see six to 10 patients per clinic list. In addition, the service is provided to a number of sports teams on an ad-hoc basis, as and when required.

At the time of our inspection, the service employed two members of staff; the owner, who was also the registered manager and a retired radiologist; and the general manager, who was also a scan operator.

We previously inspected the service on 02 April 2019, where we rated this service as inadequate and the provider was suspended for carrying out any regulated activities for eight weeks.

The service was suspended at the time of our inspection.

Activity (May 2018 – March 2019):

- Fastrack Scan did not keep detailed records of the number of scans performed. However, they told us they had performed an estimate of 1,760 scans on 770 patients in the reporting period.
- All patients were self-funded or covered by their medical insurance.
- Fastrack Scan did not keep detailed records of the number of clinics they cancelled. However, we were told that no clinics had been cancelled in the reporting period.

Track record on safety (May 2018 – March 2019):

- The service reported zero never events.
- The service had recorded zero incidents.
- The service reported zero serious injuries.
- The service received zero complaints.

Summary of this inspection

How we carried out this inspection

The team that inspected the service comprised a CQC lead inspector and an Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) inspector. The inspection team was overseen by an inspection manager and Bernadette Hanney, Head of Hospital Inspection.

Areas for improvement

Action the provider MUST take is necessary to comply with its legal obligations. Action a provider 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 provider MUST take to meet the regulations:

On the basis of this inspection, the Chief Inspector of Hospitals has recommended that the provider remain in special measures.

- The provider must ensure the safety and effectiveness of the service is monitored. Regulation 17 Good governance (1) (2) (a) (b) (f).
- The provider must ensure policies, processes and documentation relating to the service are of a high standard. They must be reflective of the service and the processes that are in place. Regulation 17 Good governance (1) (2) (b).
- The provider must ensure there is systematic programme in place to review, update and improve policies, protocols and radiation documentation such as local rules. Regulation 17 Good governance (1) (2) (a) (b).
- The provider must ensure that all documentation, policies, and evidence of training qualifications are stored. Regulation 17 Good governance (1) (2) (a) (b) (d).
- The provider must ensure that records necessary to be kept in relation to persons employed in carrying out the regulated activity contain all relevant information. Regulation 17 Good governance (1) (2) (d).
- The provider must ensure that feedback from service users and other relevant persons is used for the purposes of continually evaluating and improving the service. Regulation 17 Good governance (1) (2) (a) (b) (d) (e) (f).
- The provider must ensure there is evidence that handwashing facilities are safe for use. Regulation 17 Good governance (1) (2) (a) (b) (d) (e) (f).

Our findings

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic imaging	Inadequate	Inspected but not rated	Insufficient evidence to rate	Not inspected	Inadequate	Inadequate
Overall	Inadequate	Inspected but not rated	Insufficient evidence to rate	Not inspected	Inadequate	Inadequate

Inadequate

Diagnostic imaging

Safe	Inadequate
Effective	Inspected but not rated
Caring	Insufficient evidence to rate
Well-led	Inadequate

Are Diagnostic imaging safe?

Inadequate

We rated it as inadequate.

Mandatory training

Whilst there were plans in place for staff to complete mandatory training, staff had not completed mandatory training in key skills at the time of our inspection.

- During our previous inspection on 2 April 2019, the service did not provide mandatory training to staff operating the scanning machines. There were no processes to monitor non-compliance with mandatory training. We raised our concerns about this to the registered manager in our follow up letter. Following our inspection, the registered manager said they would be addressing mandatory training areas. During this inspection, we saw evidence that mandatory training had been booked with an independent healthcare provider but had not yet been completed at the time of our inspection.

Safeguarding

Whilst staff had not completed training on how to recognise and report abuse at the time of our inspection, this has been planned. Staff demonstrated an understanding of how to protect patients from abuse. This was an improvement since our previous inspection.

- During our last inspection, the service did not have a safeguarding policy for children or adults. We raised our concerns about this to the registered manager in our follow up letter. During this inspection, there was a safeguarding policy for adults. However, it was not dated. The policy contained relevant telephone numbers of safeguarding teams at the local authorities.
- During our last inspection, staff had not completed training in safeguarding adults and safeguarding children, with the exception of the registered manager who had undertaken safeguarding adults and children level two. The service had carried out a small number of DEXA scans on young people aged 15 and over. There was no lead for safeguarding and staff did not have access to a level three children's safeguarding lead. We raised our concerns about this to the registered manager in our follow up letter. During this inspection, the registered manager told us they had taken the decision to stop providing services to children under the age of 18. Safeguarding adults training had been booked for the scan operator however they were unable to provide a definitive date for the training.

Inadequate

Diagnostic imaging

- During our last inspection, staff we spoke with did not understand their roles and responsibilities regarding safeguarding vulnerable people. Staff could not explain safeguarding arrangements and who they would report issues to, to protect the safety of vulnerable patients. During this inspection, this information was documented within the safeguarding policy and staff could explain what they would do if they were concerned about an adult or a child in line with the policy.
- During our last inspection, we found there were no arrangements for checking all staff were fit to work with vulnerable adults and children. Essential checks had not been carried out on all staff members. The service did not carry out a Disclosure and Barring Service (DBS) check on all appointed staff. DBS is the process by which employers can check the criminal record of employment candidates. We raised our concerns about this to the registered manager in our follow up letter. During this inspection, we were told that the scan operators' DBS application had been made but the DBS had not yet been returned. Following the inspection, we saw evidence that DBS checks had been carried out on all staff.

Cleanliness, infection control and hygiene

The service had some processes to control infection risk. Staff had an improved knowledge of how they could be compliant with best practice for hand hygiene, in accordance with national guidelines. There was now an infection prevention and control policy in place and plans to complete cleaning schedules that had been developed.

- During our last inspection, there was no infection prevention and control (IPC) policy in place. During this inspection, there was a policy in place. However, it was not dated. The policy contained information about daily, weekly and monthly IPC control measures such as cleaning duties and hand hygiene.
- During our last inspection, staff were not compliant with best practice for hand hygiene, in accordance with National Institute for Health and Care Excellence QS61 (Infection prevention and control). NICE clinical guideline 139 recommends that an alcohol-based hand rub should be used for hand decontamination before and after direct contact or care. Whilst an alcohol-based hand rub was available, staff did not use it between episodes of patient care. Direct contact or care refers to face-to-face contact with patients. We raised our concerns about this to the registered manager in our follow up letter. During this inspection, we could not observe hand hygiene practices as the service was suspended at the time of our inspection. However, staff were able to articulate best practice NICE guidance regarding hand hygiene and had discussed how they were going to change their practice.
- During our last inspection, there were no suitable handwashing facilities for the service. A hand wash basin was available but was not used. Staff told us the sink ran stagnant water from the tank in the mobile unit. This meant there was a risk of legionella to both staff and patients. This had not been identified as a risk or any action taken. We raised our concerns about this to the registered manager in our follow up letter. During this inspection, we found that the registered manager had taken action to ensure there was a working hand wash basin on the mobile vehicle. Arrangements were in place to test the cleanliness and safety of the water on a regular basis however this had not yet been tested at the time of our inspection.
- During our last inspection, there were no cleaning schedules in place to ensure regular cleaning was carried out at the appropriate time. For example, we were not assured that daily floor, surface and fixture cleaning and quarterly machine/chemical cleaning of hard floors were undertaken. We were told that deep cleans consisted of an operator scrubbing the floor monthly, but we found no evidence to confirm this had occurred. We raised our concerns about this to the registered manager in our follow up letter. During this inspection, we found that cleaning schedules had been developed and were ready for use but had not yet been completed. There were checks to ensure that the equipment and the vehicle was safe for use.

Environment and equipment

Inadequate

Diagnostic imaging

The provider had suitable premises. There were handwashing facilities. Environmental risk assessments had been completed. Equipment had been serviced within the last 12 months.

- The mobile unit was a seven and a half tonne lorry which had been converted and was now used for the provision of DEXA scans. There were three steps leading into the vehicle with a portable step placed at the bottom. There were two areas; a scanning area; and a reception area used as a kitchen and waiting area, with a small table and two chairs. There was a door that could be closed to separate the scanning area and the reception area.
- There was a stairlift in working order. During our last inspection, there was no evidence that the stairlift had been serviced or an environmental risk assessment had been undertaken or that staff had adequate training. However, during this inspection we saw evidence that an assessment had been undertaken and servicing was completed in August and October 2018.
- The stairs to the van were steep. During our last inspection, we found that there had been no environmental risk assessments undertaken. We raised our concerns about this to the registered manager in our follow up letter. During this inspection, we saw evidence of the environmental risk assessments. Following the inspection, a further risk assessment was provided by the registered manager for the stairs.
- There were handwashing facilities. This was an improvement since our last inspection.
- During our last inspection, the first aid kit contained 19 items that were out of date, despite staff telling us that this had been replenished the week before inspection. These included sterile bandages and eye patches, some of which had expiry dates dating back to 2010. We highlighted this to the registered manager. We were told the out of date items would be disposed of appropriately and a new first aid kit would be purchased. We raised our concerns about this to the registered manager in our follow up letter. During this inspection, we were told that the out of date items were disposed of appropriately. The first aid kit had been replenished with necessary items and all items were within their use-by date.

Assessing and responding to patient risk

There were some arrangements in place to assess and manage risks to patients. Risks associated with radiation were displayed. Local rules were dated, displayed, and had been signed by all staff. They were reflective of current guidance. Staff had the appropriate training to manage deteriorating patients.

- During our last inspection, staff told us that the service only provided scans to patients who were low risk, and patients who were physically well and could transfer themselves to the couch without support. However, this was not outlined in the service level agreement (SLA) with an independent healthcare organisation. During this inspection, this had not improved, and the SLA had not been updated.
- During our last inspection, there was no set exclusion and inclusion criteria for DEXA scans. We raised our concerns about this to the registered manager in our follow up letter. During this inspection, the registered manager failed to provide an exclusion criteria. Following the inspection, this was provided electronically however there was no document version control. People who were unable to be seen by the provider included children under the age of 18, patients who could not transfer themselves to the couch without support and patients who lacked capacity.
- During our last inspection, staff told us that patients who lacked mental capacity would also not be seen. There was no guidance, exclusion criteria or policy for this. We raised our concerns about this to the registered manager in our follow up letter. Staff told us that if patients arrived that didn't meet the criteria, they would not be scanned, and the referring clinician would be informed. Staff did not keep a record of how often this happened. During this inspection, we saw that the exclusion criteria listed patients who 'lacked mental capacity and were unclear on the radiation risks involved with DEXA scans'.
- During our last inspection, we found that staff did not have a clear understanding of what local rules were. We were provided with documents that were titled 'local rules' that had been developed by staff, however, they were not dated, not displayed, not signed and referenced out of date guidelines. This was not in line with the Ionising Radiation

(Medical Exposure) Regulations (IR(ME)R) and Ionising Radiations Regulations (IRR) 2017 which state that every employer engaged in work with ionising radiation must, in respect of any controlled area or, where appropriate having regard to the nature of the work carried out there, any supervised area, make and set down in writing such local rules as are appropriate to the radiation risk and the nature of the operations undertaken in that area. We raised our concerns about this to the registered manager in our follow up letter. During this inspection, staff told us they had spent a number of days working with their radiation protection advisor to improve their local rules. We found the newly developed local rules were in line with and reflected current best practice guidance. They were generally appropriate for the scans being undertaken and were displayed in the scanning area. Staff had signed them. However, they were not version controlled. We were told that the local rules displayed were the most recent version.

- During our last inspection, a document we reviewed titled 'local rules' stated that "patients who are pregnant must identify to the operator that they are pregnant". Therefore, we were concerned that not all women who may be pregnant always informed a member of staff before they were exposed to any radiation in accordance with IR(ME)R. We also found that pregnant women and women who may be pregnant were not made aware of the risks associated with radiation. During this inspection, we found that action had been taken to address these issues. There were signs displayed within the waiting area and scanning area, and a clause within the new consent form which told patients they must inform a member of staff if they may be pregnant.
- During our last inspection, we found that the registered manager for the service was also the radiation protection supervisor (RPS), despite some documents stating that the general manager/scan operator was the RPS. During this inspection, we saw evidence that the scan operator had recently attended an RPS training course. The contact information for both RPS staff members was now displayed and included in the local rules for the DEXA scanning area, which was in line with best practice.
- There were employers' procedures in place which were meant to protect staff from ionising radiation. For example, staff wore an electronic personal radiation dosimeter to measure and detect radiation levels they have been exposed to. During our last inspection, we saw no evidence of the personal dosimetry reports. During this inspection, the registered manager provided us with records, which showed they were within appropriate parameters.
- During our last inspection, there were no signs or information in the waiting area informing people about areas or rooms where radiation exposure takes place. This meant there was a risk that patients and their relatives were not aware of the risks associated with exposure to radiation. We raised this during our inspection and staff told us they did not display information on the walls as they did not wish to damage the interior of the lorry. During this inspection, we saw that patient information was displayed for patients to see. For example, information about the dose of radiation, risks, reasons for not providing a patient with a lead apron and the reasons why the service will not scan pregnant patients. There were also radiation warning signs displayed, which indicated to patients and visitors that they were entering an area where radiation was in use.
- During our last inspection, we found that the scan operator did not have basic life support (BLS) training or first aid training. There was no deteriorating patient policy. Staff did not have the skills to care for a patient in the event that they became unwell or required resuscitation. Therefore, we were not reassured that staff could manage the deteriorating patient safely. We raised our concerns about this to the registered manager in our follow up letter. Following our inspection, the registered manager said the general manager/scan operator was booked on to a BLS course at the end of April 2019. During this inspection, we saw evidence that staff had BLS training.
- There was a deteriorating patient policy in place. However, the policy did not describe what procedures were in place in the event that a patient became unwell. The policy listed several signs of sepsis.
- Staff were able to tell us what they would do if a patient deteriorated. There was a mobile two-way radio system in place for use in an emergency. One radio stayed in the mobile unit and the other was kept behind the reception of the hospital site they were at that day. Staff told us that if a patient deteriorated whilst in their care, they would use the radio system to inform the hospital, commence basic life support and dial 999.

Staffing

Inadequate

Diagnostic imaging

Staff could not confirm the skills and training they had received to keep people safe from avoidable harm and to provide the right care and treatment. There was no formal certification of training undertaken.

- During our last inspection we noted that staff had not completed an induction. This was not in line with the staff handbook. Induction checklists and evaluation sheets were not provided to staff. During this inspection, we saw staff had still not completed an induction. Staff told us this was because they had been there since the service opened and therefore didn't feel it was relevant.
- During our last inspection, there was no evidence of formal DEXA training for the operators since 2009, which was a theoretical training course for IR(ME)R operators and did not include any practical training on the equipment. We raised our concerns about this to the registered manager in our follow up letter. During this inspection, we saw an email confirming that the scan operator had received applications training in 2013 however it did not describe the nature of the training or content covered. We were told that training had been provided to the scan operator at an RPS study day, but no certification was provided. This was not in line with IR(ME)R guidelines.
- During our last inspection, we found there were no cover arrangements in place for when staff were off work on holiday or sick. The registered manager told us that shorter holidays of three days at any one time were encouraged to prevent service disruption. This meant there was a risk that staff did not get a choice in how long they were off work for. However, during this inspection staff said they were given seven consecutive days off each month. This change had not been reflected in the staff handbook.
- During our last inspection, we found that staff had scanned three children in the last 12 months. However, they did not have access to a registered children's nurse that could provide advice at all times, in line with national guidance issued by the Royal College of Nursing (RCN): Defining staffing levels for children and young people's services (2013). The registered nurse does not have to be on site, however they must be reachable for advice at all times, for example, by telephone. During this inspection, the registered manager had made the decision to stop seeing children due to the lack of arrangements in place to ensure children were safe. This was reflected in the exclusion criteria.

Records

- This was not reviewed as part of this inspection.

Medicines

- This was not reviewed as part of this inspection.

Incidents

There was no clear process for managing incidents. Incidents were not investigated and details of discussions about incidents were not recorded. There was no evidence that lessons were learned and discussed with the team. The incident policy did not include the process for recording, investigating and learning from incidents.

- During our last inspection, there was no clear process in place to manage incidents. The provider did not have a policy for managing incidents. A book titled 'significant events' was used to record a summary of both risks and incidents. Due to the small size of the service, the provider told us they discussed incidents as soon as they occurred. We saw no documented evidence of this. During this inspection we found that an incident policy was in place. However, the incident reporting policy did not include the process for recording, investigating and learning from incidents.

Are Diagnostic imaging effective?

Inadequate

Diagnostic imaging

Inspected but not rated

We do not currently rate the effectiveness of diagnostic imaging services.

Evidence-based care and treatment

DEXA scans and local rules were based on national guidelines and standards. However, there was no process in place to ensure staff were following up to date guidance. No audits were carried out by the provider and no peer reviews had been undertaken.

- During our last inspection, we found that the provider's DEXA protocols were written by the registered manager. There was no system to ratify and review protocols or policies. During this inspection, we saw no improvement. Protocols and policies were not dated and there was no systematic process in place for regularly reviewing them to ensure they reflected best practice current guidance.
- During our last inspection, policies and procedures were based on out of date national guidelines. For example, radiation protection arrangements were based on Ionising Radiation Regulations (IRR) 1999 instead of IRR 2017. We raised our concerns about this to the registered manager in our follow up letter. During this inspection, we saw that policies and procedures now reflected the most current guidance. For example, local rules had been reviewed and were based on current IRR 2017 guidance.
- During our last inspection, some guidelines were not relevant to the service. For example, we saw out of date guidelines such as the Resuscitation Council guidelines issued in 2005 for advanced life support. Staff did not have advanced life support training and therefore this was inappropriate and was not based on up to date guidance. Some guidelines and policies referred to the medical director's responsibilities. There was no medical director employed by the service. We raised our concerns about this to the registered manager in our follow up letter. During this inspection, we found these guidelines had been removed. However, some documentation referred to the use of an automated external defibrillator (AED) if a patient was unresponsive. The service did not possess an AED and therefore this was not relevant.
- During our last inspection we found that there were limited policies in place. Policies that were in place, were not adhered to. For example, the radiation protection policy states "local rules will contain the name of the employer, radiation protection advisor (RPA) and supervisor (RPS), a list of controlled areas, working arrangements and contingency plans. Relevant working arrangements will be displayed in each controlled area". Local rules were not displayed, nor were they based on up to date guidelines and best practice. They did not include the name of the employer, the RPA, or the RPS. This was also not in line with best practice. We raised our concerns about this to the registered manager in our follow up letter. During this inspection, we saw this had improved. For example, the registered manager and scan operator had spent time with the RPA to ensure their practice reflected what was in their radiation protection policy. Local rules were now displayed.
- During our last inspection, there was no process in place to ensure best practice and new guidance was identified and implemented. Practice was not audited against guidelines, and there was no clinical audit programme in place. Participation in benchmarking clinical audits was also not carried out. Staff took no action to monitor the safety and effectiveness of the service provided and therefore were unable to understand where improvements were required. During this inspection, we found this had not improved. The registered manager told us they planned to audit every single scan going forward but there were no audit criteria in place and no audit schedules.

Nutrition and hydration

- This was not reviewed as part of this inspection.

Inadequate

Diagnostic imaging

Pain relief

- This was not reviewed as part of this inspection.

Patient outcomes

The service did not monitor the effectiveness of care and treatment and was therefore unable to identify and act upon areas that required improvement.

- During our last inspection, we found there was no information about the outcomes of people's care. This type of information was not collected or monitored. There was no use of audits to drive service improvements or monitor the safety and effectiveness of the service. During this inspection, we found this had not improved.
- The service did not record or monitor the time between when a referral to the service for a scan was received and that scan being performed.
- Audits of the quality of the images were not undertaken.

Competent staff

There was no documented evidence that staff were competent for their roles. Staff's work performance was not appraised. This meant that staff were not supported to be competent in their roles and the effectiveness of the service and the quality of scans were not monitored.

- There was no evidence that staff had the right qualifications, skills, knowledge and experience to do their job when they started their employment, took on new responsibilities and on a continual basis.
- During our last inspection, there was no process to identify the learning needs of staff to cover the scope of their work. The DEXA scan operators had not received an appraisal in the last 12 months or at any time since employment commenced. The registered manager had been appraised at an independent healthcare provider in 2018. During this inspection, we found that the scan operator had received basic life support training and had attended a radiation protection advisor training course. However, the scan operator had not been appraised.
- During our last inspection, we found that staff competencies were not assessed as part of the recruitment process, at induction, through probation, and then ongoing as part of staff performance management. During this inspection, we saw templates for documenting staff competencies. However, there was no supporting documentation to show how competencies would be assessed and recorded. The registered manager told us this was work in-progress.
- During our last inspection, there was no evidence of formal training for the operators since 2009, which was a theoretical training course for Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) operators and did not include any practical training on the equipment. We raised our concerns about this to the registered manager in our follow up letter. During this inspection, we were told that training had been provided to the scan operator at an RPS study day, but no certification was provided. This was not in line with IR(ME)R.
- During our last inspection, there were no equipment training records available for staff who operated imaging equipment. No staff had equipment competencies documented. There was a risk that staff may not have been competent to safely operate the equipment used. During this inspection, we saw an email confirming that the scan operator had received applications training in 2013 however it did not describe the nature of the training or content covered.
- During our last inspection, staff had not been trained and therefore did not have the appropriate skills to recognise and treat a deteriorating adult or child. During this inspection, all staff had received basic life support training.

Inadequate

Diagnostic imaging

- During our last inspection, the service did not provide a mandatory and statutory training programme for staff. This meant there was a risk that staff did not have the relevant knowledge and competencies required. During this inspection, we saw plans for staff to undertake a mandatory package of training. This included, but was not limited to, fire safety and safeguarding training.

Multidisciplinary working

- This was not reviewed as part of this inspection.

Seven-day services

- This was not reviewed as part of this inspection.

Health promotion

- This was not reviewed as part of this inspection.

Consent and Mental Capacity Act

We could not be assured that staff understood their roles and responsibilities under the Mental Health Act 1983 and the Mental Capacity Act 2005. They had not received any training at the time of our inspection. The mental capacity policy was not in line with Mental Capacity Act 2005. However, risks associated with radiation was explained. This was an improvement since our previous inspection.

- During our last inspection, we could not be assured that staff understood the relevant consent and decision-making requirements of legislation and guidance, including the Mental Capacity Act 2005 and the Children's Acts 1989 and 2004. Staff told us they would not scan a patient if they appeared confused or did not understand the scanning process. Staff were unable to provide an example of when they had refused a patient who was confused. Staff had not received mental capacity act training and there was no guidance in place for managing patients who lacked capacity. We raised our concerns about this to the registered manager in our follow up letter. During this inspection, we saw plans for staff to attend training in mental capacity as part of the mandatory training package. There was a documented formal process of what staff would do in the event that staff were concerned about a patients' ability to consent to the scan.
- A new mental capacity policy had been developed but it was not in line with the Mental Capacity Act 2005. The policy said that staff would "help people with low capacity to make a decision", despite staff not having completed training. This was also not in line with the newly developed exclusion criteria which stated that the service would not see patients that do not have capacity to make a decision. We were still not assured that staff were knowledgeable about assessing patients' mental capacity.
- During our last inspection, there was a patient history questionnaire which each patient completed prior to having a scan. The consent to the DEXA scan was given by the patient signing a clause which said "I consent to the DEXA scan", if the patient was female they also confirmed "I am not pregnant". There was a risk, given that patients were not given an explanation of risks prior to the scan, that they may not declare they are pregnant. We raised this with the registered manager, who told us they were considering developing a new consent form. During this inspection we reviewed the new consent form and information was displayed which made the risk of radiation to pregnant women clear.

Inadequate

Diagnostic imaging

Are Diagnostic imaging caring?

Insufficient evidence to rate

During this inspection, we did not collect sufficient evidence to rate caring.

Compassionate care

Staff undertook scans for patients with compassion. Feedback from patients confirmed that staff treated them well and with kindness.

- During our last inspection, there was no process to collect feedback from patients. Comments and compliments were also not recorded. However, during this inspection we saw feedback forms which were going to be handed to each patient with a stamped addressed envelope which meant they could return their feedback at no extra cost. Due to the infancy of this process, there were no clear plans in place as to how this was going to be collected, monitored or reviewed.

Emotional support

- This was not reviewed as part of this inspection.

Understanding and involvement of patients and those close to them

Risks associated, whilst low, were communicated clearly to patients. This was an improvement since our last inspection.

- During our last inspection, we found that staff communicated with patients clearly, so they understood the instructions once within the mobile unit. Patients were given verbal instructions, information about how long the scan would take and what was required from them. However, patients were not made aware of the risks associated with radiation. There was no explanation of what the scan entailed. Patients were not informed of why they needed to be weighed and measured prior to having the scan performed. During this inspection, information leaflets had been developed. Signs and written information given to patients prior to the scan explained the risks associated with radiation.

Are Diagnostic imaging well-led?

Inadequate

We rated it as inadequate.

Leadership

While the registered manager had the skills, knowledge and experience to perform DEXA scans, they had not fully established suitable and effective policies and procedures to fulfil all of the requirements of the Health

and Social Care Act 2008 (Regulated Activities) Regulations 2014 (Part 3). The service did not have managers with the right skills and abilities to run a service providing high-quality care. However, leaders had a better awareness of the employment checks and training that were required, which was an improvement since our previous inspection.

- The service was led by the registered manager who was a retired radiologist. They had previous experience in leading a DEXA service in an NHS trust. The day to day management of the mobile unit was led by a general manager who was also a scan operator.
- During our last inspection, we found that leaders did not have the skills, knowledge and experience they required to lead and manage the service safely and effectively. For example, there was no evidence that the general manager/scan operator had received the appropriate practical training to operate the scanner. The registered manager had developed a very limited number of policies, which were of poor quality, contained limited information and based on out of date guidance and regulations. During this inspection, we saw evidence that additional policies had been developed. However, whilst some policies procedures were based on best practice guidance, not all policies were of good quality. Appropriate training for general manager/scan operator was not evidenced and there was no documented summary of what training they had attended.
- Leaders had a better understanding of the challenges to quality and sustainability since our last inspection and had identified some of the actions needed to address them. However, not all actions had been completed. For example, safeguarding and mandatory training had not yet been completed.
- They had not established suitable and effective policies and procedures to fulfil the requirements of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (Part 3).

Vision and strategy

There was no vision for what the service wanted to achieve and workable plans to turn it into action.

- There was no documented vision or strategy. The service had not developed any values.
- Staff told us they hoped to expand the service and employ radiographers with recognised training experience. They recognised that an appropriate induction process would be required.

Culture

Whilst staff were friendly and welcoming, the culture was not focussed on safety and quality.

- The registered manager and staff were friendly and welcoming. They were committed to providing a caring DEXA scanning service to patients.
- Staff felt they were respected and valued by the registered manager. Staff were positive about their roles.
- During our last inspection, we found there were no mechanisms in place for providing staff with development and training. Appraisals were not completed. This meant that staff were unaware of areas of development they needed, and training required, to lead the service, and scan patients. During this inspection, there were plans in place to address this. For example, development and training had been discussed and we saw evidence that training courses had been booked. The registered manager told us this was going to be a bigger focus going forward. However, there was still no evidence of an appraisal for all staff members or a process in place for ensuring appraisals were completed routinely.

Governance

Inadequate

Diagnostic imaging

There was a lack of governance arrangements in place. The limited arrangements that were in place were not adequate to ensure high standards of care and oversight could be maintained. Systems and processes had not been established or operated effectively to assess, monitor and improve the quality and safety of the services provided to carry out the regulated activity.

- Due to the small nature of this service, there were no governance or team meetings. However, staff told us they planned to keep a record of discussions about the service delivery.
- During our last inspection, there were no personnel files for staff members. We saw no evidence of qualifications, references, and employment history. Not all staff had undergone the Disclosure and Barring Service (DBS) checks. Leaders were not aware of the importance of these checks, despite scanning children and vulnerable adults. We raised our concerns about this to the registered manager in our follow up letter. During our inspection, the registered manager had begun to gather information and placed it onto a folder titled 'personnel file'. However, records necessary to be kept in relation to persons employed to carry out the regulated activity, did not contain all relevant information. For example, there was no evidence of Disclosure Barring Service (DBS) applications, photographic identification, and references.
- During our last inspection, we could not be assured that audits of scans were undertaken, as they were not documented. We raised our concerns about this to the registered manager in our follow up letter. During this inspection, we were told scans were audited each time they were reviewed however this was still not documented and therefore there was no evidence of audit.
- During our last inspection, training required in key skills had not been identified. There was no system in place to ensure staff were up to date with their own training. For example, there was no training schedule. We raised our concerns about this to the registered manager in our follow up letter. During this inspection, we saw a training schedule template. However, there was no evidence to show that the training on the schedule had been completed.
- During our last inspection, there were very limited policies and procedures in place. For example, there was no infection prevention and control policy or safeguarding policy. There were no mechanisms in place to review key documents such as local rules, policies, and protocols. We raised our concerns about this to the registered manager in our follow up letter. During this inspection, we found that whilst some new policies had been developed, they were not of a high standard. For example, the mental capacity policy was not in line with the Mental Capacity Act 2005. Policies did not include clear processes for staff to follow. For example, the incident reporting policy did not include the process for recording, investigating and learning from incidents. The deteriorating patient policy referred solely to symptoms that could be linked to sepsis and did not include what process staff should follow in the event that a patient deteriorated for any other reason.
- Some policies were contradictory. For example, documentation provided stated that patients who weighed over 150kg would not be seen, however the weight limit for the couch was 205kg and this was also the specified weight limit documented in the patient exclusion criteria.
- Policies were not headed, dated, nor was there a systematic programme in place to review, update and improve them. Some policies had been written on, sentences crossed out, and new sentences added. There was a lack of document version control. Old and new policies were found in different folders which meant we could not be assured staff were following the most up to date policy. It was not explicit which policies were the most recent version. Some policies were printed copies of Care Quality Commission regulations. For example, a version of a safeguarding policy.
- Documentation, policies and processes were not stored systematically. Not all evidence requested was available as they were not kept. For example, certificates of training completed with the Radiation Protection Advisor.
- During our last inspection, we found that service level agreements (SLAs) were not signed. Staff were not clear about the purpose of SLAs. During this inspection, we saw no improvement.

Managing risks, issues and performance

Inadequate

Diagnostic imaging

Systems had been developed to identify, reduce and eliminate risks, and to cope with both the expected and unexpected.

- During our last inspection, we found there was not an effective process in place for reviewing and managing compliance with IR(ME)R 17 and IRR 17 regulations. For example, recommendations set out in the radiation protection advisor report had not been actioned. During this inspection, we saw some action had been taken to comply with IR(ME)R 17 guidance. For example, local rules had been improved and now reflected the nature of the service.
- During our last inspection, there were no assurance systems or performance monitoring systems in place. Safety and quality audits were not undertaken in relation to records, infection prevention and control, and environment. There was a lack of awareness of improvements that were required due to insufficient monitoring. We raised our concerns about this to the registered manager in our follow up letter. During this inspection, we reviewed a new template for carrying out safety and quality checks. For example, a daily cleaning log and back-up generator checks.
- There was no evidence that feedback from relevant persons and other persons on the services provided in the carrying on of the regulated activity was used for the purposes of continually evaluating and improving such services. For example, no patient feedback had been collected and there was no evidence of the compliments staff told us about.
- During our last inspection, environmental risks and safety risks had not been identified. For example, we identified several risks during our inspection, such as steep stairs to climb on to the vehicle and the lack of training provided and undertaken. During this inspection, we saw that some risk assessments had been carried out. For example, lone working. However, there was no risk assessments for the steep stairs. We raised this again with the provider and a risk assessment was provided.
- We saw no evidence that the impact on quality had been assessed in preparation for expanding the service.

Managing information

- This was not reviewed as part of this inspection.

Engagement

- This was not reviewed as part of this inspection.

Learning, continuous improvement and innovation

We saw some evidence of learning from previous inspection findings, plans to ensure staff completed training and improvements in infection prevention and control. However, the provider was failing to comply with Regulation 17, (1) (2), Good governance, of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

- We escalated some concerns identified on our previous inspection in April 2019 to the registered manager and the general manager/scan operator. Following our last inspection, we sent a letter detailing our concerns and notifying the registered manager of the decision to suspend the service for eight weeks.
- During this inspection, we found that the following improvements had been made and therefore the suspension expired on 03 June 2019:
- The service had begun to implement processes to control infection risk. There was an infection prevention and control policy in place and cleaning schedule templates had been developed but were not yet in use.
- There were handwashing facilities. Environmental risk assessments had been completed. Consumables stored in the first aid kit were within their use-by date.
- Risks associated with radiation were displayed. Local rules were displayed and signed by all staff and they were reflective of current IR(ME)R guidance. Staff had attended basic life support training.
- Mandatory training, including safeguarding training had been booked but had not yet been completed.

Inadequate

Diagnostic imaging

- Risks associated with radiation when undertaking scans, whilst low, were communicated clearly to patients.
- There was a formally documented exclusion criteria.
- Environmental risk assessments had been completed. Mitigating actions had been documented.
- A patient feedback form had been developed.

However, further improvements were required:

- There was no clear process for managing incidents.
- Policies in place were not of a high standard, no audits were carried out by the provider and no peer reviews had been undertaken.
- The service did not monitor the effectiveness of care and treatment and was therefore unable to identify and act upon areas that required improvement.
- There was no documented evidence that staff were competent for their roles. Staff's work performance was not appraised.
- Staff did not understand their roles and responsibilities under the Mental Health Act 1983 and the Mental Capacity Act 2005. They had not yet received any training; however, this was planned.
- There was no vision for what the service wanted to achieve and workable plans to turn it into action.
- There was a lack of governance arrangements in place. The limited arrangements that were in place were not adequate to ensure high standards of care could be maintained. There were no plans to systematically review policies, procedures and protocols. Document version control was not used and policies were not dated.
- The registered manager provided evidence of continuing professional development.
- The registered manager did not undertake any audits or peer reviews

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 17 HSCA (RA) Regulations 2014 Good governance **Regulation 17 (1) (2) (a) (b) (d) (e) (f)** • Systems and processes were not established or operated effectively to assess, monitor and improve the quality and safety of the services provided in the carrying on of the regulated activity. • During our inspection, we were told scans were audited each time they were reviewed however this was not documented and therefore there was no evidence of audit. • Policies, processes and documentation relating to the regulated activity and the service provided were not of a high standard. For example, the mental capacity policy was not in line with the Mental Capacity Act 2005. Policies did not include clear processes for staff to follow. For example, the incident reporting policy did not include the process for recording, investigating and learning from incidents. The deteriorating patient policy referred solely to symptoms that could be linked to sepsis and did not include what process staff should follow in the event that a patient deteriorated for any other reason. • Some policies were contradictory. For example, documentation provided stated that patients who weighed over 150kg would not be seen, however the weight limit for the couch was 205kg and this was also the specified weight limit documented in the patient exclusion criteria. • Policies were not headed, dated, nor was there a systematic programme in place to review, update and improve them. Some policies had been written on, sentences crossed out, and new sentences added. There was a lack of document version control. Old and new policies were found in different folders which meant we could not be assured staff were following the

This section is primarily information for the provider

Enforcement actions

most up to date policy. It was not explicit which policies were the most recent version. Some policies were printed copies of Care Quality Commission regulations. For example, a version of a safeguarding policy.

- Documentation, policies and processes were not stored systematically. Not all evidence requested was available as they were not kept. For example, certificates of training completed with the Radiation Protection Advisor.
- Records necessary to be kept in relation to persons employed in the carrying on of the regulated activity did not contain all relevant information. For example, there was no evidence of Disclosure Barring Service (DBS) applications, photographic identification, and references.
- There was no evidence that feedback from relevant persons and other persons on the services provided in the carrying on of the regulated activity was used for the purposes of continually evaluating and improving such services. For example, no patient feedback had been collected and there was no evidence of the compliments staff told us about.