

Alliance Medical Limited

Poole PET-CT Centre

Inspection report

Poole Hospital NHS Foundation Trust Longfleet Road Poole **BH15 2JB** Tel: 01202263012 www.alliancemedical.co.uk

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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	Requires Improvement	
Are services safe?	Requires Improvement	
Are services effective?	Inspected but not rated	
Are services caring?	Good	
Are services responsive to people's needs?	Good	
Are services well-led?	Requires Improvement	

Summary of findings

Overall summary

This service had not been previously inspected. We rated it as requires improvement because:

- The service provided mandatory training in key skills, but some training was considered optional but should have been mandatory. Lessons learned from safety incidents were disseminated to staff effectively, but measures to prevent reoccurrence were not always undertaken with no evidence of audit.
- There were two incidents where patients received higher than intended doses because there was no process to check the dose before administration.
- The service performed well in its programme of internal audits, but we saw many were out of date, although they were planned to be carried out by the new registered manager once in post. For example, pregnancy status and patient identification audits had not been carried out in the last a year.
- Risks on the risk register were not given clear dates for review and mitigating actions were not recorded.
- Training records did not reflect actual levels and types of training undertaken. There was no evidence duty of candour had been fulfilled in correspondence as part of a joint approach between the NHS trust and the service.

However:

- The service had enough staff to care for patients and keep them safe. Staff understood how to protect patients from abuse. The service controlled infection risk well. Staff assessed risks to patients, acted on them and kept good care records. Staff knew how to report patient safety incidents.
- Staff provided good care and treatment and gave patients enough to eat and drink. Managers monitored the effectiveness of the service. Staff worked well together for the benefit of patients. Scanning services were available five days a week.
- Staff treated patients with compassion and kindness, respected their privacy and dignity, took account of their individual needs, and helped them understand their conditions.
- The service planned care to meet the needs of local people, took account of patients' individual needs, and made it easy for people to give feedback. People could access the service when they needed it and did not have to wait for treatment. Staff went above and beyond to make adjustments to help meet the needs of individual patients.
- Leaders had the skills and abilities to run the service and were visible and approachable. They supported staff to develop their skills and take on more senior roles. The service had a vision for what it wanted to achieve. Staff at all levels were clear about their roles and accountabilities.

Summary of findings

Our judgements about each of the main services

Service Summary of each main service Rating

Diagnostic imaging

Requires Improvement



This service has not been previously inspected. We rated it as requires improvement. See the summary above for details.

Summary of findings

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Summary of this inspection

Background to Poole PET-CT Centre

Poole PET-CT centre is based at an NHS Foundation trust and is owned and operated by Alliance Medical Limited. This service performs PET (Positron Emission Tomography) and CT (Computed Tomography) scans for NHS patients from most NHS Trusts in the geographical area.

PET-CT imaging is a type of molecular imaging which provides valuable information about the structure or anatomy of the tissues being examined. By giving small quantities of a radioactive injection, PET produces images showing how the cells of the body are functioning. By combining PET and CT in single scanner, images are produced which reveal information regarding the exact location, size, nature and extent of disease anywhere in the body in greater detail.

The service operates from 07.30 am to 7.30 pm Monday to Friday.

From 1 January 2021 to 31 December 2021, the service carried out 2933 examinations. In the same timeframe, 25 patients did not attend their appointment.

The service is provided as part of a national contract issued and overseen by NHS England and Improvement.

The service is registered for the regulated activity of diagnostic and screening procedures.

This service was registered in January 2017. At the time of the inspection there was an interim registered manager covering until the new registered manager began in May 2022.

We have not previously inspected or rated this service.

How we carried out this inspection

The team that inspected this location comprised of two CQC inspectors and a specialist advisor with expertise in diagnostic radiography including nuclear medicine. We spoke with five members of staff including a registered manager from another PET-CT unit (who was supporting the unit), five patients and observed interactions with patients throughout the day. We also held an interview with the interim registered manager. We reviewed documents and records kept by the provider and inspected the scanning department. We also spoke with the Nominated Individual and Medical Director remotely.

There were no special reviews or investigations of the location ongoing by the CQC at any time during the 12 months before this inspection.

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

Outstanding practice

We found the following outstanding practice:

Summary of this inspection

- Staff used a colour coded system to alert them to which isotope was being used for scans. Any associated paperwork was also colour coded so staff could quickly see what scan each patient was attending for.
- Staff could access and use electronic tablets to provide video British Sign Language interpreters for the entire duration of a patient appointment, which was often up to two hours or more.
- An inpatient checklist had been developed and was in use to obtain essential information for those patients coming from hospitals as inpatients.
- The service completed a medical emergency scenario in June 2021 and had also completed a number of tabletop exercises using different emergency scenarios in different locations around the unit.

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 handover forms used for planned and emergency maintenance are filled out completely and in line with company policy. **Regulation 12 (1) (2) (e)**
- The service MUST make sure that patients receive the correct dosage of radiation appropriate to the examination they are having. **Regulation 12 (1) (2) (g)**
- The service MUST ensure all systems including the training matrix, risk registers and evidence of duty of candour are sufficient and record evidence all actions necessary to provide assurance the service has oversight of these key areas. **Regulation 17 (2) (b)**
- The service MUST ensure staff training records are accurate and effective. Regulation 17 (2) (d)

Action the service SHOULD take to improve:

- The service should make sure visitor toilets are safe to use and have an alarm or are accessible in the event of an emergency.
- The service should update and maintain all annual and regular audits in line with company policy and legal requirements.
- The service should attempt to obtain information about resuscitation status when patients attend from other healthcare settings.
- The service should make sure the training shows the level of safeguarding training completed by staff.
- The service should routinely audit compliance of pregnancy checks for all relevant patients.
- The service should make sure spills training is accurately recorded on the training matrix.

Our findings

Overview of ratings

Our ratings for this location are:

Our ratings for this location are:						
	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic imaging	Requires Improvement	Inspected but not rated	Good	Good	Requires Improvement	Requires Improvement
Overall	Requires Improvement	Inspected but not rated	Good	Good	Requires Improvement	Requires Improvement

	Requires Improvement
Diagnostic imaging	
Safe	Requires Improvement
Effective	Inspected but not rated
Caring	Good
Responsive	Good
Well-led	Requires Improvement
Are Diagnostic imaging safe?	

We have not rated safe before. We rated it as requires improvement.

Mandatory training

The service provided mandatory training in key skills to all staff and made sure everyone completed it. However, some key training subjects were listed as optional, so staff had not completed them.

Staff received and kept up to date with most of their mandatory training. Staff regularly undertook mandatory e-learning, which had continued without interruption during the pandemic. Where face- to-face training was required, such as immediate life support, sessions had been arranged with staff.

Requires Improvement

The mandatory training was comprehensive and mostly met the needs of patients and staff. The unit had a training matrix which showed 93% staff compliance against 17 mandatory training subjects, although one member of staff was a new starter but had the outstanding training booked. However, we saw that medicines management training had not be included as a mandatory training subject.

There was evidence all staff working with radiation had appropriate training in the regulations, radiation risks, and the use of radiation and we saw from training records, modules covering Ionising Radiation (Medical Exposures) Regulations (IR(ME)R) 2017 updates were listed as mandatory, in line with company policy. 75% of staff had undertaken this training at the time of our inspection.

Training compliance was monitored centrally by Alliance Medical. Managers monitored mandatory training and alerted staff when they needed to update their training. Staff told us when they had asked for additional or specialist training, the service supported them to attend.

Clinical staff completed training on recognising and responding to patients with mental health needs, learning disabilities, autism and dementia, although this was listed as optional training rather than mandatory.

Safeguarding

Staff understood how to protect patients from abuse and the service worked well with other agencies to do so. Staff had training on how to recognise and report abuse and they knew how to apply it.



Staff received training specific for their role on how to recognise and report abuse. Staff maintained up-to-date mandatory e-learning, which included Safeguarding Vulnerable Adults, Safeguarding Adults at Risk and Safeguarding Children modules. Training compliance was 100%, although the level of training completed was not documented on the unit training matrix. We were told all staff received level two safeguarding training for both adults and children.

Staff could give clear examples of how to protect patients from harassment and discrimination, including those with protected characteristics under the Equality Act (2010).

Staff knew how to identify adults and children at risk of, or suffering, significant harm and worked with other agencies to protect them. Staff knew how to make a safeguarding referral and who to inform if they had concerns. Staff were aware of the corporate Safeguarding Adults and Safeguarding Children Policies and referred to them if they had any safeguarding concerns. Safeguarding Leads' contacts for the adjoining NHS trust and Alliance Medical were displayed in the unit.

Cleanliness, infection control and hygiene

The service controlled infection risk well. Staff used equipment and control measures to protect patients, themselves and others from infection. They kept equipment and the premises visibly clean.

Clinical areas were visibly clean and had suitable furnishings which were also clean and well maintained. Cleaning staff accessed the department out of hours due to radioactive materials stored on site and were restricted to general areas only.

Staff cleaned equipment after patient contact and labelled equipment to show when it was last cleaned. We saw equipment cleaning was incorporated into daily cleaning checklists. In all clinical areas we saw specialist cleaning wipes and saw staff using them to clean equipment between each patient scan.

Areas where radioactive materials were kept, such as the injection preparation room and the waste storage cupboards, were cleaned by clinical staff. All restricted areas including waste storage areas were visibly clean and uncluttered.

Staff followed infection prevention and control principles, including the use of personal protective equipment (PPE). The provider had a central PPE hub based at head office and an electronic based reporting and ordering system to provide an effective and efficient stock of PPE and cleaning materials. Each week, the unit manager or clinical lead submitted a tailored request for stock depending on the units' needs and delivery was received every Wednesday. An email address had been set up for any urgent PPE needs or feedback regarding the stock.

Precautions were taken when seeing people with suspected communicable diseases such as influenza. Where a patient was known or suspected as having a communicable disease, they were given an appointment at the end of the scanning list to enable deep cleaning after their scan. Through a service level agreement with the hosting NHS Trust, staff could access deep cleaning if required.

The service used infection control measures when carrying out a consultation or performing a scan which included the use of face masks, aprons and gloves. The unit had been classed as safe and secure following completion of a COVID-19 secure risk assessment, which was reviewed quarterly. The unit carried out a monthly infection prevention and control audit and the latest monthly hand hygiene audit showed 100% compliance.

Cleaning records were up-to-date and demonstrated that all areas were cleaned regularly.



Environment and equipment

The design, maintenance and use of facilities, premises and equipment kept people safe. Staff managed clinical waste well.

Each patient cubicle had a call bell and staff explained how they responded to these but maintained a safe distance from the patient. The scan room was constantly observed during scanning. Patients could reach call bells and staff responded quickly when called.

We saw the visitor toilet did not have an alarm and had two locks on the door which meant that access would not been possible in the event of an emergency. We raised this with the unit manager on site who raised it with the hosting NHS Trust as they were responsible for the facilities.

The design of the environment followed national guidance. The design of a Positron Emission Tomography and Computed Tomography (PET-CT) unit took account of the doses of radiation administered to patients. As such, individual cubicles were required for each patient to lie in after their injection. Staff had enough space to move freely through the department but were also able to maintain safe distances from radioactive materials and patients after they had received their injection. Patients who had received their radioactive injection had their own separate toilet to use to prevent contamination for staff and other patients.

Staff carried out daily safety checks of specialist equipment. The PET-CT scanner underwent daily quality assurance checks and staff could describe what they would do if any of the checks fell outside of acceptable ranges. Other specialist equipment such as Geiger counters and the assay calibration device, were checked daily and serviced annually.

Staff disposed of clinical waste safely. Staff showed us how they monitored and stored clinical waste bags which contained radioactive waste. Staff explained radioactive clinical waste had to be stored until the level of radiation had decayed to a safe level. The waste could then be disposed of in the same way as normal clinical waste. Due to the short half-life of the radiopharmaceuticals used, staff explained they did not need to store the bags for very long, which meant the waste did not build up in the storage cupboard.

Resuscitation equipment was readily available, the trolley was adequately stocked and there was evidence of regular reviews. The unit had two emergency kits available, one of which was maintained by the hosting NHS Trust. We checked the contents of the resuscitation trolley and emergency bags and found everything listed was present and in date.

The imaging service had completed risk assessments for all new or modified uses of radiation, which were reviewed every two years or whenever a change occurred. This was last undertaken in September 2020. If there were any changes, for example, a new protocol; the risk assessment was re-reviewed.

Risk assessments addressed occupational safety as well as considering risks to people who used services and the public. For example, doses of radiation to members of the public and to patient escorts, such as nursing staff. If a member of staff or carer needed to be present during a scan, the dose of radiation they received was recorded on the electronic records system.

The service ensured controlled areas (where ionising radiation was present) were restricted to authorised personnel only. Doors to the unit were locked with key code pads to prevent unauthorised admittance.



Ionising radiation was used as part of the CT element of the scan, so ionising radiation warning lights were not on during the PET scan. There was clear signage when ionising radiation exposure occurred. However, we saw one incident reported where an agency member of staff had entered the scan room during the CT part of the scan. We reviewed the investigation report made to the radiation protection advisor, which showed the staff member had ignored warning lights and removed a physical barrier to enter the room. The report included a summary of actions taken which included direct feedback to the staff member.

The service ensured specialised personal protective equipment was available and used by staff and carers when needed. Staff showed us the syringe shields, lead screens and storage facilities for the radiopharmaceuticals and we saw staff use them to dispense and administer injections safely to patients.

The provider undertook assessments and reviews of their activities under the Control of Substances Hazardous to Health Regulations 2002.

The service had an equipment quality assurance programme for all scanning equipment and had input from a medical physics expert. Equipment was operated and maintained consistent with the manufacturers' recommendations. We saw a planned preventative maintenance schedule for both PET and CT elements of the scanner.

There were service contracts for equipment and a clear process for maintenance of equipment and for reporting of any faults. As part of each service, handover documents were done for the engineer prior to service and again from the engineer after service. Documents contained details of known issues and repairs plus a general report on the performance of the equipment. However, handover documents were not always filled out completely in line with company policy. We saw there had been 14 instances of maintenance or repair between January 2021 and February 2022. In five out of 14 reports, staff had not confirmed if processing software had been turned back on. This was an action recommended following a serious incident reported in 2019, where this software was deactivated by an engineer without staff knowledge.

The service managed aging equipment and equipment failures through a rolling capital replacement programme, which was overseen centrally at the provider headquarters. The scanner was five years old, so was not due for replacement until the end of the current contract in 2025.

The service monitored staff for radiation exposure using dosimeters. Staff wore one on their torso and a finger-based dosimeter when handling, drawing up and administering radioisotopes. Dose reports were reviewed by the registered manager on a monthly basis, and any high or outlying doses were discussed with staff. For example, if a member of staff had a high finger dose, they were offered additional support, observation and training in handling and injecting radioisotopes.

The service had a dedicated spillage kit in the case of a radioisotope spillage or significant blood spillage after administration of the radioisotope to a patient. The registered manager had provided some scenario-based training around droplet spread and spillage containment. Training records showed this had last been done in 2021. We requested the spillage policy which confirmed scenario-based training was to be completed annually. Staff told us they knew where the spillage kit was located and how to use it.

The service had an Environment Agency inspection in July 2021 with no actions, recommendations or breaches.

The service had enough suitable equipment to help them to safely care for patients. Staff explained that bariatric equipment and assistance with hoisting was available from the hosting trust if required.



Assessing and responding to patient risk

Staff completed and updated risk assessments for each patient and removed or minimised most risks. Staff identified and quickly acted upon patients at risk of deterioration.

Staff responded promptly to any sudden deterioration in a patient's health. There were clear pathways and processes for the management of people who were, or became, clinically unwell. As part of the contract with the hosting NHS trust, staff followed the same emergency call process as the rest of the trust by dialling 2222 for help. The service completed a medical emergency scenario training in June 2021. However, in addition the service had also completed a number of tabletop training exercises using different emergency scenarios, in different locations around the unit.

There were processes to ensure the right person got the right scan, at the right time. Staff printed out all referrals in advance of patients attending and called the Ionising Radiation (Medical Exposures) Regulations (IR(ME)R) practitioner licence holder (formerly Administration of Radioactive Substances Advisory Committee licence holder) or referrer if there were any queries or discrepancies on the referrals. Staff told us they knew the licence holders well, spoke to them regularly and they were readily available for advice.

The service followed the Royal College of Radiologists' Standards for the communication of radiological reports and fail-safe alert notifications. As part of the National PET-CT Contract with NHS England, the service was committed to undertaking scans and processing reports within seven days. Images were uploaded to the Alliance Medical electronic system centrally, which was accessed by the IR(ME)R licence holder or another approved reporter. Final, verified reports were automatically transferred (along with images) to the trust picture archive and communication system (PACS) on publication of the report.

Staff followed the Society of Radiographers "pause and check" guidance when checking patient's identity before administering injections or scanning the patient. This was documented by signing a form and scanning it into the booking system. The service audited compliance with identity checks and the latest audit for December 2020 showed 100% compliance but had not been completed as part of the 2021 annual audit cycle.

The imaging service ensured the radiation protection advisor and the medical physics expert were easily accessible for providing radiation advice, and occupied offices attached to the unit.

The service appointed radiation protection supervisors in departments which used ionising radiation. Staff told us they had attended specialist training to undertake the radiation protection supervisor role and felt supported by senior management.

The service ensured the 'requesting' of a PET-CT scan was only made by staff or persons in accordance with IR(ME)R. The service held a list of approved referrers and any requests received from persons not on the list were immediately escalated by the IR(ME)R practitioner licence holder for clarification.

The service adopted a referral criterion which meant they did not scan anyone under the age of 18.

The service ensured staff were aware of women who were or may be pregnant before they were exposed to any radiation in accordance with IR(ME)R and for staff in accordance with Ionising Radiation Regulations (IRR) 2017. We saw posters displayed in patient areas telling them to speak to a nuclear medicine practitioner before they were scanned.



Staff also showed us they could perform basic pregnancy tests for patients if necessary. Pregnancy status was recorded and scanned into the electronic patient record system. Compliance with pregnancy checks formed part of an annual audit. The most recent audit from December 2020 showed 100% compliance. The audit was due to be completed every six months but had not been repeated.

Patients were given information explaining how appointments were managed to minimise risks during the COVID-19 pandemic. We saw this on appointment confirmations and reminders.

There were clear processes to escalate unexpected or significant findings both at the examination and upon reporting. Images and reports were turned around within a seven-day window, so reports from scans were readily available to referrers.

The service had a set of local rules and employer's procedures available to protect staff and patients from ionising radiation. We checked these documents and saw they had recently been reviewed and signed off.

Staff knew about and dealt with any specific risk issues. Staff understood the risk associated with extravasation (where intravenous medicine leaks into surrounding tissues) and a twice monthly audit was undertaken of cannulation techniques. We reviewed the latest audits data which showed 100% compliance for all relevant staff.

Staffing

The service had enough staff with the right qualifications, skills, training and experience to keep patients safe from avoidable harm and to provide the right care and treatment. Managers regularly reviewed and adjusted staffing levels and skill mix, and gave bank, agency and locum staff a full induction.

The service had enough nuclear medicine and support staff to keep patients safe. The service had three nuclear medicine practitioners, one clinical assistant, an interim unit manager and one administrator. Additionally, there was one nuclear medicine practitioner vacancy and another administrator role was being advertised. The service had also recently appointed a new unit registered manager who was to start in the role.

The manager accurately calculated and reviewed the number of radiographers, technicians and support workers needed for each shift. The number of staff matched the planned numbers. Managers made sure bank and agency staff had a full induction and understood the service. Alliance Medical Limited supplied bank staff wherever possible to meet demand. The benefit of this was staff were already familiar with the ways of working safely and effectively. However, we saw an incident reported where an agency member of staff had entered a scan room despite all the safety precautions in place.

Agency and bank staff who worked for the service received a comprehensive induction and the service recorded training details for the staff centrally which aligned with mandatory training required by the service. Agencies supplying staff sent though details of training, and the clinical lead assessed the staff before they were signed off to work in the department.

Health Education England identified national shortages in the provision of clinical and diagnostic radiographers for cancer services. The provider ensured adequate staffing through a rolling recruitment programme from head office.

The service had a medical consultant on call during evenings and weekends. Staff could contact a radiologist or lonising Radiation (Medical Exposures) Regulations (IR(ME)R) practitioner licence holder for advice. As the centre was located in the grounds of an NHS trust, radiologists (as part of a service level agreement) were available during scanning hours.



Records

Staff kept detailed records of patients' care and treatment. Records were clear, up-to-date, stored securely and easily available to all staff providing care.

Patient notes were comprehensive, and all staff could access them easily. There were no delays in staff accessing the records. Records were stored securely.

The service ensured imaging requests were appropriate and included the relevant information to allow for requests to be justified in accordance with Ionising Radiation (Medical Exposures) Regulations (IR(ME)R). The practitioner licence holder was responsible for vetting and approving requests from a pre-approved list of referrers. Any queries or issues were followed up by the licence holder prior to being passed to the service for appointment. Staff then further checked the referral information and raised queries with the licence holder when needed.

We reviewed six patient request forms and saw all required information was present on all six forms, including protocols, medical history and clinical indication for the scan.

As part of the justification process to carry out exposure to radiation, the imaging service attempted to make use of previous images of the same persons requiring the test. The service stored images on a wider picture archive communication system, which meant they could access previous images if the patient had been scanned at any of the Alliance Medical sites. The registered manager explained they could not yet access the NHS trust's picture archive communication system which meant they did not always have access to all the patients' scans and reports when the patient attended for their scan. However, all previous images were made available to the radiologist who reported the scan.

Where appropriate, patient information was transported with patients when they attended for a scan. Staff explained referrals were first accepted onto the NHS trust's referral system for vetting then passed to the service to be uploaded onto its electronic booking system. This meant inpatients (from the adjoining NHS trust) always had their notes with them which included any treatment escalation plans or 'do not attempt cardio-pulmonary resuscitation' (DNACPR) documentation. However, patients attending from other healthcare setting such as care homes did not always bring their records, so staff did not always know if a DNACPR was in place for every patient. A request form was sent by Alliance Medical to the care home requesting the patient notes accompanied the patient.

Staff told us there were two picture archive communication systems to store images. Once the patient had their scan, all images were uploaded centrally to the Alliance Medical picture archive communication system and redirected from headquarters back to the practitioner license holder for reporting. There was a dedicated team centrally who oversaw and checked all images were sent withing the seven-day target under the NHS England Cancer contract.

Medicines

The service used systems and processes to safely prescribe, record and store medicines. Staff had undertaken medicines management training.

The service had processes to ensure the right radiopharmaceutical and activity was sourced, prepared and injected into the correct patient. Radiopharmaceuticals were ordered in advance and according to the vetted request. Depending on the number of patients on the list for the day, the service could have up to three separate deliveries of radiopharmaceuticals. This was because the half-life of the isotope was quite short and would not last all day. Staff manually drew up and checked the activity of the injection using a tool on the booking system which helped calculate the volume of radiopharmaceutical to draw up based on the time of injection and half-life of the radioisotope. Injections



of radioisotopes were administered in line with the IR(ME)R operator checklist for Administration of Radioisotopes for Molecular Imaging Procedures. We also saw two incidents reported of doses being given to patients which were higher than the dose reference levels. In both cases, the staff in question were spoken to and reminded of the dose protocols for the service.

Staff followed systems and processes to administer, record and store medicines in line with the provider's policy. Staff used a colour coded system to indicate which radiopharmaceutical was in use which was also reflected in the colour of the patient's paperwork. Staff used prefilled syringes to deliver saline flushes after administering the radiopharmaceuticals.

The service had an Ionising Radiation (Medical Exposures) Regulations (IR(ME)R) audit schedule, which was last completed in December 2020 and should be repeated annually in line with legal requirements under IR(ME)R 2017. Staff explained the audit was being included in the handover for the new unit registered manager to undertake once they assumed their role in March 2022.

Radiopharmaceuticals and other medicines were stored correctly. We saw a lead safe in the radiopharmaceutical preparation room where the vials of radiopharmaceutical fluorodeoxyglucose were stored prior to injection.

The service worked in line with the Society of Radiographers (SoR) guidance referencing and worked in line with the "IR(ME)R operator checklist for Administration of Radioisotopes for Molecular Imaging Procedures. There were two clinical staff who administered radioisotopes as part of clinical nuclear procedures that had appropriate, specific training and demonstrated competence in the appropriate procedures (British Nuclear Medicine Society Professional Standards Committee, 2016). However, we found medicines management was optional training for staff on the online platform. Of the two staff this applied to, both had undertaken the training. This meant staff maintained their competency to administer radiopharmaceutical medicines in keeping with the provider's medicines quality policy and procedures (2021). A third member of clinical staff was in the process of performing induction training and was therefore not administering radiopharmaceutical medicines. All clinical staff administering medicines had completed Health Education England e-Learning for Health Medicines Management training.

Radiologists held appropriate IR(ME)R practitioner licenses for the administration of each radiopharmaceutical. These licenses were stored and coordinated centrally at the provider headquarters to ensure they were up-to-date and reflected the types of examinations being undertaken in the service. We reviewed the license for the unit and found it was in date. Information in them reflected the examinations undertaken with a clear line of delegation for injecting radiopharmaceuticals. We also saw the documents giving authority to order and inject radiopharmaceuticals referenced the correct licence certificate numbers.

Incidents

The service managed patient safety incidents well. Staff recognised incidents and near misses and reported them appropriately. Managers investigated incidents and shared lessons learned with the whole team and the wider service. Managers ensured that actions from patient safety alerts were implemented and monitored but were not always effective. When things went wrong, staff apologised and worked with organisation to give patients honest information and suitable support.

Staff knew what incidents to report and how to report them. All staff members had access to the incident reporting system. There was a clear policy and pathway to guide staff to identify and report incidents. The service had not recorded any never events. There had been no serious incidents reported in the past twelve months. Staff received feedback from investigation of incidents through the providers 'Risky Business' newsletter every month.



Managers shared learning with their staff about incidents and learning that happened at the centre. A serious incident had occurred in 2019 which was investigated and found that patients had been harmed as a result. Following a routine service, a setting on the scanner had been changed which altered the appearance of the scans produced, which meant some scans had been incorrectly reported. As a result of this incident, a clear set of actions had been established including a check box on the maintenance handover forms to indicate that all software was installed and working. Staff we spoke to were aware of this incident and the learning from it. However, we saw the handover forms were not being consistently filled out.

Staff understood the duty of candour, but it was not always fulfilled when things went wrong, and the service did not directly give patients and families a full explanation or apology. Following the serious incident in 2019 and in discussion with several NHS trusts and NHS England, the decision was made for duty of candour to be carried out by the referrer from the NHS trust, in line with The Royal College of Radiologists position statement in relation to duty of candour in diagnostic imaging (October 2015). Senior staff explained this decision had been made as it was felt the referrer had the best relationship to explain the error and its implications for each patient affected. We saw in the incident investigation and in meeting minutes the service had pledged support to the referrers and had provided a statement to include in subsequent letters which included an apology. However, the service did not have evidence the statement had been used in any correspondence to the patient.

Staff reported incidents clearly and in line with the service's policy and received feedback from investigations. Staff met to discuss the feedback and look at improvements to patient care. For example, we saw feedback from incidents all around the business were shared on a monthly basis through a 'risky business' newsletter.

Managers investigated incidents thoroughly, but action taken was not always effective. We reviewed incidents reported from November 2021 to 23 February 2022. We saw two incidents where agency staff had entered the scan room whilst a scan involving ionising radiation was taking place. We reviewed the investigation for one of these incidents which showed the staff member had been asked to re-read the local rules. However, another similar incident occurred a month later involving the same member of agency staff.

There had been no incidents reportable under Ionising Radiation (Medical Exposures) Regulations (IR(ME)R) in the 12 months prior to our inspection.

Are Diagnostic imaging effective?

Inspected but not rated



We inspect but do not currently rate effective for diagnostic imaging.

Evidence-based care and treatment

The service provided care and treatment based on national guidance and evidence-based practice. Managers checked to make sure staff followed guidance.

Staff followed up-to-date policies to plan and deliver high quality care according to best practice and national guidance. Policies and procedures were made available to staff at provider and site-specific level for the service. For example, in



relation to Ionising Radiation Regulations 2017, which regulate the protection against exposure to ionising radiation due to staff roles. The scanning protocols and procedures were reviewed and approved by a consultant radiologist and Ionising Radiation (Medical Exposures) Regulations (IR(ME)R) practitioner license holder in the case of positron emission tomography (PET) scanning.

Staff understood and followed best practice guidance including Ionising Radiation (Medical Exposure) regulations 2017 (IR(ME)R).

The service ensured radiation doses were kept as low as reasonably practicable. Doses for each PET scan were pre-defined and measured to ensure the correct amount of radiopharmaceutical was used for each patient. Dose reference levels were clearly displayed in the lab and the former unit registered manager undertook an annual audit of doses, to ensure they were within legal limits. We requested the last audit but it was not provided.

The service had an image optimisation team who reviewed around 10% of scans for each centre per month. Images were graded one to five, one being the poorest score and five the highest. Image and reporting quality were audited within the service and compared to national outcomes across the organisation. We requested the latest image quality audit which showed that between January 2021 and December 2021, the service reviewed 320 scans of which 301 (94%) received grade five (the highest quality grading). This compared with an average of 90.8% across all Alliance Medical PET-CT centres nationally. No scans at Poole were graded one or two.

The service ensured it identified and implemented relevant best practice and guidance, such as National Institute for Health and Care Excellence (NICE) guidance. Staff signed to say they had read and understood the policies and procedures. When policies and procedures were updated, staff were advised by the organisation or registered manager of the change and often updated policies were highlighted and discussed at team meetings. Significant changes were also discussed as part of weekly 'bronze' calls which all registered managers in Alliance Medical Limited attended. These calls were also recorded and disseminated across the organisation.

Nutrition and hydration

Staff gave patients enough food and drink to meet their needs and improve their health. They used special feeding and hydration techniques when necessary. The service made adjustments for patients' religious, cultural and other needs.

Staff made sure patients had enough to eat and drink including those with specialist nutrition and hydration needs. Patients were provided with specific instructions relating to eating and drinking prior to their scan within the appointment/booking information. This included fasting and only drinking water for a period of time.

There were facilities for hot and cold drinks plus biscuits for patients after they had their scan. Patients were recommended to sit in the waiting room while they had a drink and biscuit before leaving their appointment.

The service had processes for vulnerable patients who required pre-examination fasting or drinking. Diabetes management was considered at the initial safety review. If patients had type one diabetes, they were booked for their scan late morning. This enabled the patient to have their insulin, breakfast and then have nothing orally for four hours. Patients with type two diabetes had earlier morning appointments to enable them to miss medicines and breakfast and so be suitably fasted for their appointments. The blood sugar levels of patients could be checked on arrival at the centre if required.



Pain relief

Staff assessed and monitored patients regularly to see if they were in pain, and to see if they were comfortable.

The scanning procedures were painless, but staff monitored and checked with patients throughout the scan to ensure they were comfortable. Staff assisted patients to access the scanning machine and helped position them appropriately.

No pain-relieving medicines were available within the service.

Patient outcomes

Staff monitored the effectiveness of care and treatment. They used the findings to make improvements and achieved good outcomes for patients. The service had been accredited under relevant clinical accreditation schemes.

Staff always had access to up-to-date, accurate and comprehensive information on patient's care and treatment. All staff had access to an electronic records system (including bank and agency staff) they could all update, although the service did not have access to the acute trust radiology booking system on the site.

The service participated in relevant national clinical audits. The service regularly reviewed the effectiveness of care and treatment through local audit and national audit with a structured audit programme. These audits included a monthly hand hygiene, an annual image quality and an annual Ionising Radiation (Medical Exposures) Regulations (IR(ME)R) audit. The service was accredited by the Quality Standards for Imaging.

All PET-CT reporters were included in the national programme of audit scheme. This was a randomised 10% surveillance audit undertaken by auditors independent to the reporting clinicians. This was a centrally coordinated audit process carried out by the organisation. The results were held centrally, with feedback provided throughout the year to reporters to allow for reflection and improvement of practice.

Competent staff

The service made sure staff were competent for their roles. Managers appraised staff's work performance and held supervision meetings with them to provide support and development.

Staff were experienced, qualified and usually had the right skills and knowledge to meet the needs of patients. New staff were provided with induction training, which included a one-day corporate induction and managers gave new staff a full induction tailored to their role before they started work. A mentor was allocated to new staff and provided support with their induction programme and through their six-month probation period.

Staff had the opportunity to discuss training needs with their line manager and were supported to develop their skills and knowledge. Managers supported staff to develop throughout the year with constructive appraisals of their work. All staff working at the service over the past year had received an annual appraisal.

The annual appraisal was linked to a pay review and completed jointly by the staff member and the registered manager. Topics discussed included mandatory training, core values and behaviours, career conversation, and a learning development review. A further mid-year review of individual objectives also took place.



Managers made sure staff received any specialist training for their role by identifying any training needs their staff had and gave them the time and opportunity to develop their skills and knowledge. All staff had undertaken either undergraduate or postgraduate training in nuclear medicine and had attended further training courses to learn new skills. For example, staff were given the opportunity to attend a variety of specialist courses at a centre of excellence in cancer care. Role specific training was available to staff in addition to the mandatory training.

It was optional for staff to complete training on recognising and responding to patients with mental health needs, learning disabilities, autism and dementia. Dementia awareness and Mental Capacity Act training did not appear on the mandatory list of training subjects' staff were expected to maintain. However, we saw all staff had completed this training.

Staff who administer radiopharmaceutical medicines as part of clinical nuclear procedures should receive appropriate, specific training and demonstrate competence in the appropriate procedures (British Nuclear Medicine Society Professional Standards Committee, 2016). However, we found medicines management was optional training for staff.

The service ensured relevant staff continued to maintain registration with relevant bodies. Managers also explained if a staff member was required to submit evidence of their continuous professional development as part of their revalidation, they would be given time and support during work hours to complete this. The service held records to show the professional registration for the clinicians was checked annually with the professional body. For example, radiographers were registered with the Health and Care Professions Council.

Role specific continuous development and maintenance of existing skills and competencies was an ongoing process. For example, peripheral vascular device insertion. Audits took place monthly to ensure staff maintained their competency and provided good outcomes for patients during their appointment at the centre.

Multidisciplinary working

Doctors, nurses and other healthcare professionals worked together as a team to benefit patients. They supported each other to provide good care.

Staff contacted wards, surgeries and other health care professionals to discuss any specific health care needs in preparation for the scan. They telephoned all patients or their carers to discuss the preparation needed and confirmed the conversations with an email or letter.

Staff worked closely with referring consultants from the acute trust and Ionising Radiation (Medical Exposures) Regulations (IR(ME)R) practitioner licence holders and other designated reporters. Liaison and communication took place by telephone, email and in face-to-face meetings.

A twice-yearly radiation protection committee meeting was held where the medical physics expert and/or the radiation protection advisor from the acute trust attended. The purpose of the meetings was to identify various topics for discussion including emergency contingency plans, any reported radiation incidents and review of the monthly radiation scenario training provided to staff. We saw minutes of these meetings, which showed they were consistently attended, that last being February 2022. Managers explained meeting minutes were held centrally, but we also saw key themes and highlights shared with all staff. All meeting minutes were made available to staff on a central database.

Seven-day services

Key services were available to support timely patient care.



The service provided PET-CT scans on Monday to Friday from 07.30 am to 7.30 pm. The unit manager present for the inspection explained that demand for the service was growing again and that avenues to expand capacity were being explored, including staffing requirements.

Health promotion

Staff gave patients practical support and advice to lead healthier lives.

There was limited health promotion available to patients in the centre as information provided related to the procedure being undertaken. Patients were advised not to smoke for six hours prior to the scan and were provided with information regarding when they could eat or drink, before and after the scan.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

Staff supported patients to make informed decisions about their care and treatment. They followed national guidance to gain patients' consent.

Staff gained consent from patients for their care and treatment in line with legislation and guidance. Staff understood how and when to assess whether a patient had the mental capacity to make decisions about their care. If staff felt a patient lacked the capacity to consent to the procedure, they would seek further advice. Patients were provided with written and verbal information prior to their appointment to enable them to understand the planned diagnostic test.

Staff knew how to support patients who lacked capacity to make their own decisions or were experiencing mental ill health, and we saw training records supported this. A checklist for inpatients had been created, which took account of mental capacity, so staff were aware of any concerns in advance of the patient's scan.



We have not rated caring before. We rated it as good.

Compassionate care

Staff treated patients with compassion and kindness, respected their privacy and dignity, and took account of their individual needs.

Staff were discreet and attentive when caring for patients. Staff took time to interact with patients and those close to them in a respectful and considerate way. Each patient was provided with an individual room, known as the uptake room, to change into any gown or clothing needed. Each cubicle had a basket for the patients' belongings to be stored safely. Music was available in the rooms whilst the patient waited for their scan. The rooms had closed circuit television (CCTV), which was covered by a curtain when patients were changing. The CCTV was used to enable patient's privacy but also so staff could ensure their safety. There was signage to inform patients of the use of CCTV.

Patients said staff treated them well and with kindness. We saw staff spoke to patients in a friendly and considerate manner and gave a high standard of care. Patients were offered a chaperone if requested. All five patients we spoke with made positive comments about staff. One patient said that treatment by staff "could not be better".



Staff followed policy and kept patient care and treatment confidential. A room was available if patients wished to have a private conversation on arrival or at any point during their time in the department.

Staff understood and respected the personal needs of patients and how they may relate to care needs. Staff provided longer appointment slots to patients who needed them. Staff made sure necessary equipment was available to help patients with mobility difficulties.

Emotional support

Staff provided emotional support to patients, families and carers to minimise their distress. They understood patients' personal, cultural and religious needs.

Staff gave patients help, emotional support and advice when they needed it. All five patients we spoke to said that staff had been helpful and supportive. Staff supported anxious patients by arranging for them to see the scanner before their appointment date. Staff provided patients choices to listen to music and wear eye masks to reduce stress during scans. Staff signposted patients with high anxiety to their GP for a low dose of sedative to take before their scans.

Staff supported patients who became distressed in an open environment and helped them maintain their privacy and dignity. Staff explained that sometimes patients did not know if they were claustrophobic, so if a patient could not tolerate their scan, staff worked with them to either re-attempt the scan or to rebook and directed the patient to obtain mild sedation from their GP.

Staff understood the emotional and social impact a person's care, treatment or condition had on their wellbeing and on those close to them. Patients told us staff understood the sensitive nature of the treatment and took this into account when speaking to them.

Understanding and involvement of patients and those close to them Staff supported patients, families and carers to understand their condition and make decisions about their care and treatment.

The centre specialised in PET-CT scans and staff ensured any specific concerns were addressed before scanning commenced. For example, how radioactive they would be and for how long.

Staff made sure patients understood their care and treatment. All five patients we spoke to said staff had explained care and treatment clearly. One patient said, "the process was explained to me every step of the way". Another patient said she had received helpful leaflets and information to help her prepare for her appointment. Staff could provide written information to patients in different languages and in large print.

Patients and their families gave positive feedback on the service and their treatment and staff supported them to do this. Staff supported patients to make advanced decisions about their care as patients were provided with information in before their appointment to inform them about the treatment procedure and were available for any queries.

Staff talked with patients in a way they could understand, using communication aids where necessary. All five patients we spoke to said that staff had given them clear information. One patient said, "communication is very good". Staff used electronic tablets, hearing loops, and translation services to aid communication.

Patients and their families could give feedback on the service and their treatment and staff supported them to do this. We reviewed recent feedback that showed between January 2021 and December 2021, 98.4% of patients were either



satisfied or very satisfied with their experience. In addition, staff had undertaken a patient engagement survey, which had begun in November 2021 and was still running at the time of the inspection. This survey showed that 242 out of 243 patients were either satisfied or very satisfied with their care. One patient had stated they were extremely unsatisfied, however comments left by the patient were positive.

Staff supported patients to make advanced and informed decisions about their care. Patients told us they were provided with a wide range of documentation to explain their treatment and we saw staff gained their consent and explained each procedure.

Are Diagnostic imaging responsive?	
	Good

We have not rated responsive before. We rated it as good.

Service delivery to meet the needs of local people

The service planned and provided care in a way that met the needs of local people and the communities served. It also worked with others in the wider system and local organisations to plan care.

Managers planned and organised services, so they met the changing needs of the local population. The service was commissioned by an acute NHS trust to patients referred through the NHS and as part of a national cancer contract through NHS England.

The service provided PET-CT scans performed by specialist staff on five days a week.

Facilities and premises were appropriate for the services being delivered. The environment was appropriate, and patient centred. The waiting room was a good size and seating was available for the number of patients and relatives attending the clinic and allowed for social distancing. There was one toilet available, for patients and visitors to use before the patients had their injections. There was another toilet exclusively for patients receiving radiopharmaceuticals, to prevent the risk of cross contamination.

The service had systems to help care for patients in need of additional support. For those patients coming from the inpatient wards, timing was considered to support their other medical needs. For example, patients' medicines and treatments were considered and appointments fitted around the needs of the patient as well as dietary needs including for diabetic patients where fasting was required. Information was gathered using a dedicated inpatient questionnaire.

Managers monitored and took action to minimise missed appointments. Information about the unit and the procedures were provided with the appointment details. Staff were also available by telephone to discuss any concerns. When booking appointments, staff considered the time and location of each patient. The first appointments of the day were often used for people in the local area. This meant if the appointment needed to be cancelled, the staff would ring the patient and delay them leaving, instead of patients already travelling a longer distance. Patients arriving by ambulance were accommodated in line with availability of transport.



Managers ensured patients who did not attend appointments were contacted. From 1 January 2021 to 31 December 2021 there were 25 appointments where the patient did not attend. This data was monitored centrally, and we saw the report also held specific information about why an appointment was missed. Managers explained if there was no obvious reason for the missed appointment, they would contact both the referrer and patient to seek to re-appoint the scan as soon as possible if it was still required.

There was enough car parking, including disabled parking, available nearby to the centre on the hospital site with charges set by the acute trust. Public transport was available and accessed the hospital site.

Staff explained that from time to time appointments had to be rearranged at very short notice when the radiopharmaceutical failed part of its quality assurance. Alliance medical had four national sites for radiopharmaceutical production, but also had a contract with another independent provider who could dispense radiopharmaceuticals in the event of quality assurance (QA) failure. Whilst on our inspection, three patients had to be rebooked for the following day and three had to have their appointments pushed forward for this reason.

Emergency scanning slots were kept each day in case of urgent or inpatient referrals or to accommodate re-booked patients in the event of radiopharmaceutical QA failure.

Meeting people's individual needs

The service was inclusive and took account of patients' individual needs and preferences. Staff made reasonable adjustments to help patients access services. They coordinated care with other services and providers.

Staff made sure patients living with mental health needs, learning disabilities or dementia, received the necessary care to meet their needs. All staff had undertaken training in dementia awareness; however, it was not considered part of the mandatory training subjects required by the provider.

Information was provided to service users before appointments, which included contact details, hospital map and directions, consultants name and any information about fasting required. We asked staff if easy read information was available, but they were unsure. Where a patient's first language was not English, translation services either by telephone or face to face were used. Staff told us relatives were never used to translate due to the complexity and safety of the scans.

Staff understood and applied the policy on meeting the information and communication needs of patients with a disability or sensory loss. For patients who were visually impaired, staff ensured an appropriate person would be able to read the safety questionnaire and consent questions and complete the form on the patient's behalf. Guide dogs were able to enter the building but no further than the waiting area.

The service managed care of vulnerable service users by allowing a double appointment and therefore twice the time, for patients living with dementia or learning disabilities. For patients who required support from their carer, they were able to stay with the patient for the PET scan but not for the CT scan. However, the carer would be able to talk to the patient from the control room.

Patients who suffered with claustrophobia could find the scan daunting. Patients were encouraged to visit their GP and obtain a prescription for a sedative. The staff liaised with the patient regarding the optimum time to take the sedative to correspond with the scan time. Additionally, staff told us they would invite patients into the scanner to see and lie in it before their actual appointment.



There was access to communication aids to help patients become partners in their care and treatment. The service had information leaflets available in other languages spoken in the local community or an 'easy read' format. Staff also told us how they were able to access a British Sign Language interpreter for a patient with hearing loss and impaired speech. Through the use of a tablet, the interpreter was able to sign for and to the patient during the whole duration of their appointment.

Translation and interpretation services were available on request through a telephone service line for patients whose first language was not English. A hearing loop was available at reception and was portable and could be moved around the unit.

Access and flow

People could access the service when they needed it and received the right care promptly. Waiting times for treatment were in line with national standards.

Managers monitored waiting times and made sure patients could access services when needed and received treatment within agreed timeframes and national targets. The contract was commissioned by NHS England and required patients to be scanned and the images, together with the associated report, returned to the referring clinician within seven days of receipt of the referral. The exception to this was if there was a clinical indication for the scan to be booked for a specific date, such as treatment or surgery. At the time of inspection, 73 patients were waiting for their scan, the longest had been waiting since December 2021. Staff explained that patients remained on the waiting list until they had their scan, even if the scan was postponed for a valid reason.

Managers worked to keep the number of cancelled appointments to a minimum. Over the past year, 815 appointments had been cancelled or rescheduled. This was mainly due to failure of patient transport; the radioisotope not being delivered on time or being delayed by the manufacturing process. Many of the reasons recorded for cancellations and rescheduled appointments were outside of the service's control. This included failure in the manufacture of the radioisotope, which accounted for 272 of the appointments. The radioisotope was a form of natural elements used to pass through the body and be detected by the scanner. A leaflet was sent to patients explaining the process of the isotope being made in a facility in North Staffordshire and transported by road to the centre. Of the 815 appointments cancelled or rescheduled, only 21 were for a non-clinical reason.

The service managed 'did not attend' rates. When patients did not attend a pre-booked scan, a reminder letter was sent with a further appointment. Staff attempted to telephone the patient to establish the reason for the absence and make sure the scan was rebooked. Should contact not be successful or the second appointment not attended, the administrative staff contacted the referrer and discussed the next course of action.

Managers and staff worked to make sure patients did not stay longer than they needed to. When patients had their appointments cancelled at the last minute, managers made sure they were rearranged as soon as possible and within national targets and guidance. Two scans slot were held each day for urgent and re-arranged appointments.

Patients were offered a choice of appointments and appointments were available in other areas, to ensure patients were seen promptly. Administrative staff discussed capacity across the region. If it was not possible for a patient to be seen in Poole, they were allocated an appointment, with the patient's agreement, in another centre.

Same day or next day appointments were available if needed. The patient was contacted by telephone to complete the booking process. Where reasonable, the next available appointment space was allocated. If needed, a longer working day was planned to meet demand.



Patients were kept informed of any delays once they arrived in the department. Patients were given the choice to wait or come back in a set amount of time later.

The diagnostic service ensured it supported achievement of national cancer waiting standards, including implementation of rapid diagnostic and assessment pathways. As part of the monitoring process under the NHS England national cancer contract, the service reported on its reporting turnarounds on a weekly basis to NHS England. Data showed between 1 January 2021 and 31 December 2021, 89.5% of NHS patients had their report turned around in under seven days.

Learning from complaints and concerns

It was easy for people to give feedback and raise concerns about care received. The service treated concerns and complaints seriously, investigated them and shared lessons learned with all staff.

The service clearly displayed information about how to raise a concern in patient areas. The organisations 'concerns and complaints' leaflets were available in reception. Patients told us should they need to raise any concerns or a complaint they would start by speaking to the staff.

Staff understood the policy on complaints and knew how to handle them.

The service had an in-date complaints and concerns policy stating the roles, responsibilities and processes for managing complaints. The interim registered manager was responsible for dealing with all complaints. Complaints were initially responded to within two days by telephone or email depending on patient preference. The unit had few complaints and a high level of patient satisfaction.

Managers investigated complaints and identified themes and where appropriate, shared feedback from complaints with staff and learning was used to improve the service.

Staff could give examples of how they used patient feedback to improve daily practice. Staff had undertaken an engagement survey which had begun in November 2021 and was still running at the time of the inspection. This survey showed that 242 out of 243 patients were either satisfied or very satisfied with their care. As a result of patient feedback, we saw radios had been placed in the uptake rooms to allow patients to listen to music whilst they waited for their scans.

Are Diagnostic imaging well-led?

Requires Improvement



We have not rated well-led before. We rated it as requires improvement.

Leadership

Leaders had the skills and abilities to run the service. They understood and managed the priorities and issues the service faced. They were visible and approachable in the service for patients and staff. They supported staff to develop their skills and take on more senior roles.

Leaders had the skills, knowledge, experience and integrity they needed both when they were appointed and on an ongoing basis. The interim registered manager had to split the time between two centres whilst the service waited for



the new registered manager to start. However, this was a temporary arrangement and staff said the interim manager was accessible and approachable to staff. Support was provided to the interim registered manager by a regional manager. The regional manager and interim registered manager met every two months. This provided the regional manager with the opportunity to speak to staff on site during their visit. Staff we spoke with were aware of the leadership roles and understood the reporting structure.

The interim registered manager had been provided with a comprehensive handover from the outgoing registered manager which included and oversight of incidents, risks and audits. The interim registered manager understood the needs of the service well, through attending regional and national meetings and liaising with the commissioners of the service. However, it was not clear how the new registered manager would be made aware of priorities for the service once they started in post. We spoke to the interim registered manager who was unsure of the process to handover priorities to the new registered manager.

Vision and Strategy

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

The provider had a clear vision and a set of values, with quality and sustainability as the top priorities. The organisation had developed a corporate vision, values and strategy which had been shared with the staff. A strategy wheel had been produced by the organisation together with information booklets which had been provided to staff. The interim registered manager described the aim, which was to engage staff and improve communications across the organisation. Leaders understood the challenges to quality and sustainability, and they could identify the actions needed to address them.

Culture

Staff felt respected, supported and valued. They were focused on the needs of patients receiving care. The service promoted equality and diversity in daily work and provided opportunities for career development. The service had an open culture where patients, their families and staff could raise concerns without fear.

The staff we spoke with during inspection were open and friendly and spoke positively about working at the unit. They felt supported, respected, valued and proud to work for the organisation.

The service sought more information when patients' feedback showed dissatisfaction. We reviewed five policies and procedures and saw all had equality impact assessments completed. This ensured they had considered the needs of staff and patients and reflected on the potential effects the policy may have on people with protected characteristics.

The provider conducted a survey of staff, 'Response to the Pandemic Survey 2021' where 78% respondents agreed or strongly agreed with the statement that they were proud to have been part of Alliance Medical Limited response to the pandemic.

Staff were aware of the providers whistleblowing policy and the service had a freedom to speak up guardian.



Governance

Leaders operated governance processes, throughout the service and with partner organisations, but they were not always effective. Staff at all levels were clear about their roles and accountabilities and had regular opportunities to meet, discuss and learn from the performance of the service.

Governance arrangements for monitoring staff training were not effective. Training records did not accurately reflect mandatory training compliance. Staff were required to undertake spills training which they did through a series of scenarios in September 2021 but was not recorded on the central training matrix which showed compliance as 0%.

There was no evidence the duty of candour statement provided to NHS trusts had been used in any duty of candour correspondence between the NHS trust and the patient affected.

The certificate for the administration of radioactive medicinal products, which was issued to the overseeing consultant for the unit and contained in the providers procedure for delegating radiopharmaceutical responsibility, had been renewed in 2020 and we saw the new license number was reflected on both the authority to inject and authority to order schemes of delegation in line with legal responsibilities.

Checks and audits were carried out to assess the quality of the service provided to patients. The centre underwent an annual quality assurance inspection, which showed an overall compliance score of 95%. The service did not have a target to achieve but excellent was considered over 95% and good 80-94.5%. Areas identified for improvement centred mostly around updating some risk assessments and audits. For example, the fire risk assessment completed by the host site had expired in August 2020. The registered manager had chased the trust monthly for completion and we saw this was now in date.

There were structures, processes and systems of accountability to support the delivery of the strategy and good quality, sustainable services. Staff at all levels were clear about their roles and understood what they were accountable for, and to whom. Policies and procedures were available to staff on the company website and were reviewed regularly and updated in line with national guidance and legislation. Staff could demonstrate how to access policies and guidance when needed.

Medical physics support was provided by the hosting NHS trust and the department directly joined the PET-CT department. Staff were clear on who their radiation protection advisor and medical physics expert were and could describe how to contact them. We saw evidence in incident logs of the medical physics experts' input in incidents involving radiation or requiring advice.

The service ensured all staff underwent appropriate checks as required by Schedule 3 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. Staff were recruited in line with national guidance and the effective recruitment process ensured staff were competent, capable and confident in their area of practice. The registered manager was supported in the recruitment processes by the organisation's human resources department. Checks on staff continued professional registrations, where applicable, were undertaken annually.

Feedback was given to the unit during quality calls and unit managers across Alliance Medical Limited. They met monthly to talk about recent audits, changes or learning from incidents and patient feedback.



Management of risk, issues and performance

Leaders and teams did not always use systems to manage performance effectively. They identified and escalated relevant risks and issues but did not record identified actions to reduce their impact. They had plans to cope with unexpected events.

The provider had a current incident management framework and associated procedures policy. The unit had a risk register with 30 risks. All the risks were all opened between April 2020 and June 2021. There was no review date recorded on the register. All risks had a target or current risk rating. We requested minutes of the weekly 'bronze' calls in which all registered managers in Alliance Medical Limited attended for evidence of discussion of risk. We saw they showed comprehensive discussion of serious incidents and learning shared from all areas of the business. Following the inspection, we saw a new template was being introduced which had sections for review dates, target ratings and mitigations and controls currently in place.

The interim registered manager said they had identified a risk, as there were not enough administration staff for the unit and had therefore recruited an additional administration assistant who was due to start in March 2022.

The provider had a programme of clinical and internal audit to monitor quality and operational issues.

The service had back up emergency generators in case of failure of essential services. Although it would not be possible to scan on the emergency generator as it did not create sufficient output to power the scanners.

The service had remote primary and acute care system support from 07.30 am and 7.30 pm, five days a week. Scanning did not take place outside of these hours. Staff were aware of how to contact picture archive communication (PACS) support if needed.

Information Management

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

The unit had simple systems all staff could access. Staff demonstrated how easy it was to pull data from the system and could present this in several formats to help with understanding and analysis of the unit's day-to-day running.

Quality information was collated through patient, referrer and staff surveys, clinical audits, service reviews and key performance indicators. The service had an established electronic information and patient record system and systems were password protected.

The service had a range of policies including medicines quality, information security and procedures relating to radioactive materials and licences. The confidentiality of electronic patient information was maintained, and staff had access to the general data protection regulation policy.

The website for the location needed updating to include patient information in an easy read format.

Engagement

Leaders and staff actively and openly engaged with patients, staff, the public and local organisations to plan and manage services. They collaborated with partner organisations to help improve services for patients.



Patient's views and experiences were gathered and acted on to shape and improve the services and culture. The unit asked for feedback following each scan. Feedback was used to evaluate the service and the feedback we reviewed was mostly positive.

Staff meetings were held each month. Staff told us a variety of things were discussed including serious incidents, feedback from the 'risky business' newsletters and key messages from registered manager bronze calls. Local issues such as overtime and late finishes were also discussed.

There was transparency and openness with all stakeholders about performance and the latest Quality Accounts 2020/21 were available on the providers website to download.

Learning, continuous improvement and innovation

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

Leaders and staff strived for continuous learning, improvement and innovation through participating in further education at cancer specialist hospitals. The provider encouraged staff to actively seek out further education to improve delivery of the service.

Managers planned continuous development of the unit by increasing the size of the team, exploring increases in capacity and were involved in various research trials and the development of different types of scans they could undertake to improve patient experience.

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment Regulation 12 (2) (g) of the Health and Social Care Act 2008 (regulated Activities) Regulations 2014 Staff did not always check the amount (dose) of radiopharmaceutical prior to administration. There had been incidents where doses given to patient had been higher than pre-defined limits. Regulation 12 (2) (e) of the Health and Social Care Act 2008 (regulated Activities) Regulations 2014 Checks put in place following a serious incident were not being carried out consistently to ensure equipment was safe to use following servicing or maintenance. We saw that between January 2021 and February 2022, in five out of 14 reports, staff had not confirmed if the Q clear software had been turned back on. This meant staff would not know if the software had been turned off accidentally prior to scanning patients.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance
	Regulation 17 (2) (b) of the Health and Social Care Act 2008 (regulated Activities) Regulations 2014
	Multiple systems including the training matrix and risk register were not sufficient and did not evidence all actions necessary to provide assurance the service had oversight of these key areas. Risk registers did not contain review dates or evidence of sentrals or mitigation for each risk which was not in line.
	controls or mitigation for each risk which was not in line

This section is primarily information for the provider

Requirement notices

with company policy, which stated all risks were to be reviewed annually.

The training matrix used to monitor training compliance did not reflect actual training undertaken with two key areas showing 0% compliance when in fact all staff had undertaken the training.

The service did not have written evidence that they had fulfilled their responsibilities under the Duty of candour following a serious incident in 2019.

Regulation 17 (2) (d) of the Health and Social Care Act 2008 (regulated Activities) Regulations 2014

Governance arrangements for oversight of staff training were not effective and did not reflect actual training undertaken.

Mandatory training data held for staff was accurate, however where training was optional, records did not reflect actual training which had taken place.