

Northampton PET/CT Centre

Quality Report

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This report describes our judgement of the quality of care at this location. It is based on a combination of what we found when we inspected and a review of all information available to CQC including information given to us from patients, the public and other organisations

Ratings

Overall rating for this location

Good 

Are services safe?

Good 

Are services effective?

Are services caring?

Good 

Are services responsive?

Good 

Are services well-led?

Good 

Summary of findings

Letter from the Chief Inspector of Hospitals

Northampton PET/CT Centre is operated by Alliance Medical Ltd. The service provider has a registered location with an acute hospital trust.

The service provides diagnostic imaging services, positron emission tomography–computed tomography (PET-CT) to the local community. We inspected diagnostic imaging services at this location. Positron emission tomography–computed tomography is a nuclear medicine technique which combines, in a single gantry, a positron emission tomography scanner and an x-ray computed tomography scanner, to acquire sequential images from both devices in the same session, which are combined into a single superposed image. Positron emission tomography (PET) scans are used to produce detailed 3-dimensional images of the inside of the body. The images can clearly show the part of the body being investigated, including any abnormal areas, and can highlight how well certain functions of the body are working. PET scans combined with CT scans produce more detailed images. PET scanners work by detecting the radiation given off by a substance injected into the patient's arm called a radiotracer as it collects in different parts of the body. In most PET scans a radiotracer called fluorodeoxyglucose (FDG) is used, which is like naturally occurring glucose (a type of sugar) the body treats it in a similar way. By analysing the areas where the radiotracer does and doesn't build up, it is possible to work out how well certain body functions are working and identify any abnormalities. For example, a concentration of FDG in the body's tissues can help identify cancerous cells because cancer cells use glucose at a much faster rate than normal cells.

We inspected this service using our comprehensive inspection methodology. We carried out an unannounced inspection on 31 October 2018.

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.

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

The only service provided at this location was diagnostic imaging.

Services we rate

We previously did not have the authority to rate this service. We rated it as good overall.

We found the following areas of good practice:

- There was a focused and individual approach to patient care.
- We observed staff to be caring, kind and engage appropriately with patients.
- There was a strong team approach to multidisciplinary working.
- Staff told us they received feedback from incident reporting processes. We saw evidence of change to practice from incident investigation.

However, we found areas of practice that the service needed to improve:

- We were not assured staff were aware of the Ionising Radiation Regulations 2017 (IRR17) and the Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R17). On the day of inspection, staff were initially unable to locate the document to show to inspectors.
- We were not assured the standards of practice (SOP) available to staff on the intranet and in a folder to the office were up to date and referenced the IRR17 and IR(ME)R17. Once located following advice from a manager, the SOP shown to inspectors referenced the 2000 regulations.

Summary of findings

Following this inspection, we told the provider that it should make improvements, even though a regulation had not been breached, to help the service improve. Details are at the end of the report.

Amanda Stanford

Deputy Chief Inspector of Hospitals (Central)



Overall summary

The provision of PET/CT scanning services, which is classified under the diagnostic imaging and endoscopy core service was the only core service provided at this service. We rated this core service as good overall. There were systems, processes and practices essential to keep patients safe identified, put in place and communicated to staff. Care records were written and managed according to best practice. In most cases, relevant and current evidence-based guidance, standards, best

practice and legislation was used to identify and develop how services, care and treatment were delivered. Information about the outcomes of patient's care and treatment was routinely collected and monitored. There were governance frameworks to support the delivery of good quality care. However, we were not assured staff working with radiation had appropriate training in the regulations, radiation risks, and use of radiation.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Location	Good 	
Diagnostic imaging	Good 	<p>The provision of PET-CT scanning services, which is classified under the diagnostic imaging core service was the only core service provided at this service. We rated this core service as good overall. There were systems, processes and practices essential to keep patients safe identified, put in place and communicated to staff. Care records were written and managed according to best practice. In most cases, relevant and current evidence-based guidance, standards, best practice and legislation was used to identify and develop how services, care and treatment were delivered. Information about the outcomes of patient's care and treatment was routinely collected and monitored. There were governance frameworks to support the delivery of good quality care. However, we were not assured staff working with radiation had appropriate training in the regulations, radiation risks, and use of radiation.</p>

Summary of findings

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Good 

Northampton PET/CT Centre

Services we looked at

Diagnostic imaging

Summary of this inspection

Background to Northampton PET/CT Centre

Northampton PET/CT was registered in August 2016. The service provides diagnostic imaging examinations using PET-CT imaging equipment.

The service provides PET-CT scanning services for patients aged 16 years and above.

The service has had a registered manager in post since registering with the CQC in August 2016.

Our inspection team

The team comprised a CQC lead inspector who had completed the single speciality diagnostic imaging training and a specialist advisor. The inspection team was overseen by Phil Terry, Inspection Manager and Bernadette Hanney Head of Hospital Inspection.

Information about Northampton PET/CT Centre

- The location was registered to provide the following regulated activity:
 - Diagnostic and screening procedures.
- During the inspection, we visited the registered location at an acute NHS Hospital. We spoke with six staff including, administration staff, radiographer, assistant and senior managers. We observed four PET-CT scans and engaged with patients and relatives during these procedures. During our inspection, we reviewed four patient records. There were no special reviews or investigations of the service ongoing by the CQC at any time during the 12 months before this inspection.
- The service was registered with the CQC in August 2016 and this was the first inspection since registration.

Activity (September 2017 to August 2018)

- There were 1,400 positron emission tomography-computed tomography (PET-CT) scans performed at the service. All were commissioned by NHS England.
- A 0.5 whole time equivalent (WTE) unit manager, one PET-CT technologist one PET-CT radiographer and two clinical assistant/bookings administrators worked at the service on permanent contracts.

- Controlled medicines were not used and therefore they did not have an accountable officer for controlled drugs (CDs).

Track record on safety, between August 2017 and July 2018.

- There were no never events reported.
- No serious incidents.
- No IR(ME)R/IRR reportable incidents.
- No incidences of healthcare acquired Methicillin-resistant Staphylococcus aureus (MRSA).
- No incidences of healthcare acquired Methicillin-sensitive Staphylococcus aureus (MSSA).
- No incidences of healthcare acquired Clostridium difficile (C. difficile).
- No incidences of healthcare acquired Escherichia coli (E-Coli).
- The service had received seven complaints.

Services accredited by a national body:

- The service currently had three accreditations by national bodies:

Name of Accredited Body Date of Accreditation Date of Renewal

ISAS	July 2018	July 2021
ISO27001	June 2018	June 2021

Summary of this inspection

IIP March 2017 March 2020

Services provided under service level agreement:

- Clinical and or non-clinical waste removal.
- Laboratory services.
- Interpreting services.
- Maintenance of medical equipment.

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

We rated safe as good because:

- Staff received effective mandatory training in the safety systems, processes and practices.
- There were systems, processes and practices essential to keep patients safe identified, put in place and communicated to staff.
- Standards of cleanliness and hygiene were maintained.
- The design, maintenance and use of facilities and premises prevented patients from avoidable harm.
- There were comprehensive risk assessments carried out for patients who used services and risk management plans developed in line with national guidance.
- There were sufficient numbers of staff with the necessary skills, experience and qualifications to meet patients' needs.
- Patients' individual care records were written and managed according to best practice.
- Arrangements were in place for managing fluorodeoxyglucose (FDG) and fluoroethylcholine (FEC) that protected patients from avoidable harm.
- There was an effective system in place for reporting incidents. Staff understood their responsibilities to raise concerns, to record safety incidents, concerns and near misses.

However,

- We were not assured staff working with radiation had appropriate training in the regulations, radiation risks, and use of radiation.
- Staff were unable to provide evidence of training and were unaware of the Ionising Radiation Regulations 2017 (IRR17) and the Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R17). They were also unable to direct us the IRR regulations.
- While there were processes in place to ensure the right radiopharmaceutical was injected, on the day of inspection, a lone radiographer was administering fluorodeoxyglucose (FDG) to patients. There was no opportunity for a second clinician to check the dosage prior to administering.

Good



Are services effective?

We currently do not rate effective, we found:

Summary of this inspection

- In most cases, relevant and current evidence-based guidance, standards, best practice and legislation was used to identify and develop how services, care and treatment were delivered.
- There were no nutrition services provided by the unit for patients that attended for PET-CT scans. However, patients had access to bottled water in reception and in the waiting/ treatment rooms.
- Patients were asked by staff if they were comfortable during their appointment.
- Information about the outcomes of patient's care and treatment was routinely collected and monitored.
- 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.
- Staff were appropriately involved in assessing, planning and delivering patient's care and treatment.
- The service operated on Mondays, Wednesday and Fridays.
- Information leaflets such as understanding your PET-CT scan were sent to patients with their appointment letters and were available in the waiting rooms.
- Staff understood the relevant consent and decision-making requirements of legislation and guidance, including the Mental Capacity Act 2005 and the Children Acts 1989 and 2004.

However,

- We were not assured the standards of practice (SOP) available to staff on the intranet and in a folder to the office were up to date and referenced the Ionising Radiation Regulations 2017 (IRR17) and the Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R17). The SOP shown to inspectors referenced the 2000 regulations.

Are services caring?

We rated caring as good because:

- Staff understood and respected patient's personal, cultural, social and religious needs, and took these into account.
- Staff understood the impact that a patient's care, treatment or condition had on their wellbeing and on their relatives, both emotionally and socially
- Staff communicated with patients to ensure that they understood their care, treatment and condition.

Good



Are services responsive?

We rated responsive as good because:

Good



Summary of this inspection

- Information about the needs of the local population was used to inform how services were planned and delivered.
- Patients' individual needs were accounted for. Staff delivered care in a way that took account of the needs of different patients on the grounds of age, disability, gender, race, religion or belief and sexual orientation.
- Patients had timely access to scanning. Since opening in August 2016, the service had worked closely with the acute trust team to improve the quality of the service provided.
- Patients we spoke with told us they knew how to make a complaint or raise concerns about the service. Complaints were responded to in a timely way.

Are services well-led?

We rated well-led as good because:

- Leaders had the skills, knowledge, experience and integrity to manage the service.
- The provider had a clear vision and a set of values. Is there a clear vision and a set of values, with quality and safety the top priority.
- The registered manager promoted a positive culture that supported and valued staff, creating a sense of common purpose based on shared values.
- There were governance frameworks to support the delivery of good quality care.
- There was a risk assessment system in place locally with a process of escalation onto the corporate risk register.
- Electronic patient records were kept secure to prevent unauthorised access to data however authorised staff demonstrated they could be easily accessed when required.
- The service gathered patients' views and experiences and used these to shape and improve the services and culture.

However,

- Staff working with radiation were provided with training in the regulations, radiation risks, and use of radiation. Staff were not aware of the changes made by the introduction of the Ionising Radiation Regulations 2017 (IRR17) and the Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R17) which had been introduced in February 2018.

Good



Detailed findings from this inspection

Overview of ratings





Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic imaging	Good	N/A	Good	Good	Good	Good
Overall	Good	N/A	Good	Good	Good	Good

Notes

We do not rate effective.

Diagnostic imaging

Safe	Good 
Effective	
Caring	Good 
Responsive	Good 
Well-led	Good 

Are diagnostic imaging services safe?

Good 

We rated this service as **good**.

Mandatory training

- Staff received effective mandatory training in the safety systems, processes and practices. At the time of inspection, 90% of staff were compliant with their mandatory training. This met the compliance standard expected by the service.
- Most training was delivered as an e-learning module. However, staff attended face to face training for immediate life support.
- There was a system in place to ensure there was always staff members on duty with the correct level of resuscitation training. All staff supporting patients as part of the clinical pathway were required to complete immediate life support (ILS), this included paediatric basic life support (BLS). Staff told us were required to attend this training on their day off but received payment for these extra hours. The training compliance for ILS was 90% at the time of the inspection. There was one staff member whose ILS training was out of date, we saw evidence their training was booked for the week following out inspection.
- A contemporaneous training record was available for all staff and was reviewed by their line manager. Staff were emailed to prompt them to book to update their training, three months and one month prior to their training expiring.
- Mandatory training subjects included:
 - Complaints handling.
 - Conflict resolution.

- Equality and diversity.
- Fire safety at work.
- Health and safety awareness.
- Infection control.
- Information governance.
- Managing violence and aggression.
- Manual handling objects.
- Medicines management in imaging.
- Moving and positioning patients.
- The mandatory equality and diversity training, provided staff awareness of the potential needs of patients with any of the following needs: mental health, learning disabilities, autism and dementia.
- All staff working at the service were expected to complete the local induction process that covered local requirements such as knowledge of the local rules document, fire evacuation plan, local staff facilities and access codes to relevant areas.
- We were not assured staff working with radiation had appropriate training in the regulations, radiation risks, and use of radiation. Staff were unable to provide evidence of training and were unaware of the Ionising Radiation Regulations 2017 (IRR17) and the Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R17) and were unable to direct us to the IRR regulations.
- Following a telephone conversation with a regional manager we were directed to the regulations, radiation risks, and use of radiation documents stored on the intranet. However, we found the standards of practice (SOP) available to staff on the intranet were out of date, they referenced the 2000 regulations. The document had been reviewed in August 2017, prior to the 2017 Ionising Radiation Regulations guidance being issued in February 2018. The SOP was due for review in 2020.

Safeguarding

Diagnostic imaging

- There were systems, processes and practices essential to keep patients safe identified, put in place and communicated to staff.
- There were arrangements in place to safeguard adults and children from abuse that reflected relevant legislation and local requirements. Staff were trained to recognise adults at risk and were supported with an effective safeguarding adults' policy in place that reflect relevant legislation and local requirements. Staff we spoke with demonstrated they understood their responsibilities and adhered to safeguarding policies and procedures. Staff were aware of their responsibilities surrounding female genital mutilation (FGM).
- Contact numbers for local adult and child safeguarding referrals were displayed in the control room.
- There were processes in place to ensure the right person received the right imaging procedure or radiological scan at the right time. The service checked three points of identification and used the society of radiographers pause and check guidance.
- There was a system in place to ensure there were always staff members on duty with the correct level of safeguarding training. At the time of the inspection, 100% of staff had been trained in safeguarding children level one and two. The unit did not treat patients who were under the age of 18. This met intercollegiate guidance 'Safeguarding Children and Young People: Roles and competencies for Health Care Staff' (March 2014). Guidance states all non-clinical and clinical staff who have any contact with children, young people and/or parents/carers should be trained to level two. All staff had been trained in safeguarding adults level one and two.
- There had been no incidences of a healthcare acquired infection between October 2017 to October 2018.
- The unit team cleaned the scanning rooms at the end of each day. Cleaning was recorded on a daily check sheet which was reviewed by the unit manager each week. We observed appropriate cleaning procedures in place for all PET-CT equipment, following use.
- Northampton PET/CT Centre was subject to regular, infection, prevention control (IPC) monitoring requirements in accordance with policy and procedure. The unit achieved and maintained a good standard across all areas. The annual IPC audit 2018-19 benchmark was 90%. The centre achieved a score 95% in the annual IPC audit in the August 2018 audit.
- We observed staff to be compliant with best practice regarding hand hygiene, and staff were noted to be bare below the elbow. There was access to hand washing facilities. We observed staff washing their hands using correct hand hygiene techniques before, during and after patient contact. Patients told us staff always washed their hands prior to attending to them. Hand sanitiser gels were available in reception and in all rooms. Information charts about hand hygiene were displayed throughout the service. The service met National Institute for Health and Care Excellence (NICE) QS61 statement 3: People receive healthcare from healthcare workers who decontaminate their hands immediately before and after every episode of direct contact or care. Hand hygiene audits were undertaken to measure compliance with the World Health Organisation's (WHO) 'Five Moments for Hand Hygiene.' These guidelines are for all staff working in healthcare environments and define the key moments when staff should be performing hand hygiene to reduce risk of cross contamination between patients. The hand hygiene audit had been completed for all clinical staff every month during the reporting period, July 2017 to July 2018, the mean score was 100%. Hand hygiene results were communicated to staff at team meetings and through email.
- Sharps disposal bins (secure boxes for disposing of used needles) were located as appropriate across the service which ensured the safe disposal of sharps, for example needles. They were all clean and not overfilled. Labels were correctly completed to inform staff when the sharps disposal bin had been opened.

Cleanliness, infection control and hygiene

- Standards of cleanliness and hygiene were maintained. The service had infection prevention and control (IPC) policies and procedures in place which provided staff with guidance on appropriate IPC practice, for example, communicable diseases and isolation.
- There were reliable systems in place to prevent and protect patients from a healthcare-associated infection. There were safety systems, processes and practices in place and these were monitored and improved when required.
- The registered manager was the infection control lead for the service.

Diagnostic imaging

- Staff were trained in cannulation and explained to us the need to monitor cannula sites. They also told us about the process, for removing the cannula and we observed them disposing of them correctly in a contaminated sharps container.
- The Insertion of Peripheral Vascular Device (PVD) audit had been completed for all clinical staff every month during the reporting period 12 months July 2017 to July 2018, the mean score was 100%.
- The patient referral pathway for Northampton PET/CT Centre did not restrict referral of infectious patients. Where infectious patients were referred they were managed in compliance with policy for example, deep cleaning was carried after the scan, Scans were reported through the incident reporting policy to allow trend analysis. No trends had been identified and no areas of concern had been noted in the reporting period.
- All staff were compliant with the on-line annual IPC training module.
- Legionella Testing (Health and Safety) was carried out as per local policy.
- An annual deep clean was carried out by an external service through a corporate contract. We saw evidence to assure us this had been completed.
- The service had a 128 Slice PET-CT 710 scanner. This system used scintillation crystal technology, which allowed 'time of flight' PET imaging, which improved lesion detectability in smaller nodules using QCLEAR technology; reduced patient radiation dose and reduced scan times for longer imaging procedures for example 'total body scans' took approximately 35 to 40 minutes compared to 50 to 60 minutes (on previous 2D scanners).
- A control/observation area allowed visibility of all patients during the scan and close circuit televisions allowed staff to observe and monitor patients in the treatment rooms following administration of FDG. Fringe fields were displayed. (The fringe field is the peripheral magnetic field outside of the magnet core. Depending on the design of the magnet and the room a moderately large fringe field may extend for several meters around, above, and below an MR scanner).
- There was sufficient space around the scanner for staff to move and for scans to be carried out safely. Patients had access to an emergency call buzzer, ear plugs and defenders during scanning, music could be played. A microphone allowed contact between the radiographer and the patient always.
- Arrangements for managing waste and clinical specimens protected patients from avoidable harm. This included classification, segregation, storage, labelling, handling and, where appropriate, treatment and disposal of waste. Staff used the correct system to handle and sort different types of waste and these were labelled appropriately.
- The systems, processes and practices that were essential to prevent patients from avoidable harm were identified, put in place and communicated to staff. Implementation of safety systems, processes and practices were monitored and improved when required.
- All equipment conformed to the relevant safety standards and had been regularly serviced. Electrical equipment had been appropriately tested.
- Resuscitation equipment was readily available and easily accessible. The resuscitation trolley was owned and managed by the local trust was in the corridor beside the reception area. Daily and weekly checks carried out, demonstrated the equipment was safe and fit for use. There were procedures in place for removal of a collapsed patient and we reviewed evidence of evacuation practices which were performed twice yearly.

Environment and equipment

- The design, maintenance and use of facilities and premises prevented patients from avoidable harm. The layout of the unit was compatible with health building note (HBN06) guidance. Health building notes give best practice guidance on the design and planning of new healthcare buildings and on the adaptation/ extension of existing facilities.
- The service was accessible through the acute hospital's nuclear medicine department. The department had clear signage and visual prompts to assist with patients and visitors attending the service. Access to clinical areas were protected with doors secured with a keypad entry system.
- Parking was available on site at the acute trust but at a cost to the patients.
- Maintenance and use of equipment protected patients from avoidable harm. We looked at eight items of equipment, they all had a sticker indicating when they had been last serviced and when the next service was due. Equipment we looked at had an up to date service record which provided information on when an item was due to be serviced.

Diagnostic imaging

- Arrangements were in place to ensure that the premises had arrangements to restrict access and control the area where there was ionising radiation. We saw radiation warning signs were correctly located outside the clinical diagnostic imaging area. Signs on the door explained safety rules. A physical barrier was put across the door when the PET-CT was in use. Chemical products deemed as hazardous to health were in locked cupboards or rooms that were only accessible to authorised staff.
- Emergency pull cords were available in areas where patients were left alone, such as toilets and treatment room. Call bells were available within the scanning which patients could press if they wanted the scan to stop.
- There was twenty-four-hour, seven-day picture archiving and communication system (PACS) support, there were backup arrangements in the event of an IT failure.
- Clinical staff told us they felt confident to identify and respond appropriately to changing risks to patients who used services, including deteriorating health and wellbeing or medical emergencies. All clinical staff had received immediate life support training.
- There were clear pathways and processes for staff to assess patients using services in radiology departments who were clinically unwell and need hospital admission. For example, Alliance Medical Ltd (AML) Management of Medical Emergencies Policy and Procedure were available to guide staff in referring patients to an emergency department.
- Radiation risks to patients were managed in line with guidance from the International Atomic Energy Agency (IAEA) The Committee on Medical Aspects of Radiation in the Environment (COMARE 16th report): Review of radiation dose issues from the use of CT published 14 August 2014
- The service ensured that women (including patients and staff) who were or may be pregnant always informed a member of staff before they were exposed to any radiation in accordance with IR(ME)R. We saw evidence if the possibility of pregnancy could not be excluded, the patient was asked whether her menstrual period was overdue. Low dose procedures could continue to be undertaken, provided that the women's period was not overdue, which met national guidance. Information was sent out to the patient at the time of booking the appointment and there were notices up in the reception, waiting area and corridors.
- There clear pathways and processes for the assessment of patients using services within radiology who are clinically unwell and required hospital admission.
- An audit of Radiation Protection Arrangements at the Northampton PET Centre was carried out in June 2018. This audit reviewed the centre's departmental procedures, protocols and practices against the legislative requirements and associated guidance. The radiation employer for the centre was AML. The Radiation Protection Adviser (RPA) and Medical Physics Expert (MPE) were appointed under contract from Northampton General Hospital (NGH). The centre was operated and staffed by AML, including the unit manager who was appointed as the Radiation Protection Supervisor (RPS). The audit identified the recommendations from the recent patient dose audit should be implemented.

Assessing and responding to patient risk

- There were comprehensive risk assessments carried out for patients and risk management plans had been developed in line with national guidance. For example, we saw evidence of a patient safety questionnaire being completed prior to any scan. Risks were managed positively and updated appropriately where a change in the patient's condition was required for example, managing a patient who was very anxious about the procedure or had a needle phobia.
- No patients had required urgent transfer for emergency care between October 2017 and October 2018.
- Staff used The Society of Radiographers (SoR) "Paused and Checked" system. To reduce the risk of referrer error. Pause and Check consisted of the three-point demographic checks to correctly identify the patient, as well as checking with the patient the site/side to be imaged, the existence of previous imaging and for the operator to ensure that the correct imaging modality is used.
- The potential risks of intravascular administration of FDG were assessed against the potential benefits. Systems were in place which included trained individuals that can recognise and treat severe reactions, including anaphylaxis.

Diagnostic imaging

- The service had named staff fulfilling the essential roles of radiation protection advisor, medical physics expert, radiation protection supervisor, senior radiologist and infection control lead. The service had appointed a radiation protection supervisor (RPS). Staff said the radiation protection advisor (RPA) and the medical physics expert (MPE) were readily accessible online or through the telephone for providing radiation advice.
- There were local rules (IRR) and employer's procedures in place (IR(ME)R) which protected staff and patients from ionising radiation. However, these had not been updated since the introduction of the 2017 regulations. The service's local rule referenced 2000 regulations.

Staffing

- There were sufficient numbers of staff with the necessary skills, experience and qualifications to meet patients' needs. An AML staffing requirement to support a safe scanning pathway standard of practice (SOP) was in place, this enabled the unit to effectively maintain safe staffing levels and ensured there were sufficient numbers of suitably qualified, skilled staff to carry out daily tasks. The policy and procedure outlined how the headcount (actual number of staff on duty) and full time equivalent (FTE) numbers were to be calculated and managed at unit level. To achieve this the minimal amount of staff required locally for a full scanning day was two technologists/radiographers and one clinical assistant, having minimum of two staff qualified in the management of medical emergencies and recognition of the deteriorating patient, to provide a safe service to patients. All staff had completed relevant clinical competency assessments in relation to their role. To support patient safety, all members of staff had been ILS trained, undertaking courses recognised by the Resuscitation Council UK (RCUK).
- Staffing at the service comprised, a part time, 0.5 whole time equivalent (WTE) unit manager, who was a radiographer, one PET-CT technologist, one PET-CT radiographer and two clinical assistant/bookings administrators. All staff were employed on permanent contracts.
- The staffing policy ensured the service operated safely and effectively, with the appropriate number of staff and correct skill mix levels required to facilitate safe care.
- The service had 'lone working' policy and risk assessment process. On the day of inspection, the service was 'single handed scanning' where a

radiographer worked only with a clinical assistant. This was due to a member of the team being on planned leave. We observed as stated in AML staffing requirements to support a safe scanning pathway standard of practice and the local Business Continuity Plan, the service had reduced the number of scans booked. This allowed staff to take regular breaks to ensure the adequate rest was maintained. To support the calculation of local staff requirements in the different roles, the service used a staff calculator. This ensured sufficient staff were available during operational periods.

- No appointments had been cancelled because of staffing issues between August 2017 and August 2018.
- At the time of inspection, there were no vacancies within the service. Since August 2017, one WTE PET-CT technologist had left the service and one WTE PET-CT technologist had joined the service.
- Between August 2017 and July 2018, the average sickness rate for the service was reported as 2.56% for radiographers.
- The service had not used any bank staff to cover times of staff shortage between August 2017 and July 2018. However, we were told, if bank or agency staff were required, prior to undertaking any shifts they had to complete a period of induction and have proof of completion of mandatory training relevant to the position they were required to fill, and previous equipment experience to establish suitability.
- The unit manager was also the manager for another diagnostic unit relatively locally and could flex regular staff cover across both units to cover leave. This ensured staff continuity and familiarity with the unit.
- Each service was managed by an experienced operational manager, supported by regional management and central support functions, to maintain 24-hour accountability for safe and appropriate staffing levels.

Medical staffing

- The service did not employ any medical staff. All reporting consultants worked for local NHS trusts.

Records

- Patients' individual care records were written and managed according to best practice.
- We reviewed four patient records. Records were accurate, complete, legible, up to date and stored

Diagnostic imaging

securely. Records were electronic and available for access by staff. Paper records such as paper referrals were shredded as per policy once the information was uploaded.

- The radiology information system and picture archiving and communication system used by the service was secure and password protected. Each staff member had their own personally identifiable password.
- Patient and clinical information was recorded on the provider's electronic records system. This system is not integrated with the commissioner's (NHS England) data management system however there was a secure system in place to ensure necessary information was shared such as reports and images from the PET-CT Scan. The report was also shared with the commissioner via a secure NHS.net account for administration purposes. This process was managed by the provider's image transfer team and case management.
- The quality of images was peer reviewed locally by the acute trust and quality assured on a corporate level. Any deficiencies in images were highlighted to the member of staff for their learning. However, this was very rare, and the services re-scanning rate was negligible.

Medicines

- Arrangements were in place for managing fluorodeoxyglucose (FDG) and fluoroethylcholine (FEC) that protected patients from avoidable harm. This included obtaining, prescribing, recording, handling, storage and security, dispensing and disposal.
- We were not assured there were sufficient checks to ensure patients received the correct dosage of the radioactive drug, or tracer. A PET scan uses a small amount of a radioactive drug, or tracer, to show differences between healthy tissue and diseased tissue. The most commonly used tracer is called fluorodeoxyglucose (FDG), so the test is sometimes called an FDG-PET scan. Before the PET scan, a small amount of FDG is injected into the patient. There were processes in place to ensure the right radiopharmaceutical was injected however, on the day of inspection, a lone radiographer was administering fluorodeoxyglucose (FDG) to patients. There was no opportunity for a second clinician to check the dosage prior to administration. While there were checks when the radiopharmaceutical was dispensed, drawn up and level of radioactivity measured, a final four or five-way check immediately prior to injection of patient verses,

demographics, verses intended exam, verses radioactive medicinal products (RMP) identity verses RMP activity, would be a useful 'fail-safe'. We raised this with senior staff during the inspection.

- Medicines were stored securely within a designated room and were stored at the correct temperatures, in line with the manufacturers' recommendations, to ensure they would be fit for use.
- Staff were trained on the safe administration of intravenous FDG and FEC. We reviewed staff competency files and saw all staff had received this training. We observed three patients receiving intravenous FDG during our inspection, their allergies were documented and checked on arrival in the unit.
- The service did not use any controlled medicines for any of their procedures and therefore did not have a controlled medicines policy in place.
- The service did not use Patient Group Directions (PGDs).
- The Society of Radiographers (SoR) recommended "Paused and Checked" system was used to check medications prior to administration.
- Emergency medicines were available in the event of an anaphylactic reaction. These were in date.
- The registered manager was the service lead for the safe and secure handling of medicines.
- Patients were given patient information post scan which documented which medications they had been given. This directed patients to seek advice from their GP or A&E if feeling unwell after leaving the unit and explained they should show the information regarding what they had received.
- The pharmacy team at the local acute trust was available for assistance and advice locally if required.
- The service had a consultant pharmacist who issued guidance and support at a corporate level and worked collaboratively with the clinical quality team on all issues related to medicines' management.
- Medication and disposal was provided by an external company on a contract.
- The service ensured that the medicines (administration of radioactive substances) regulations 1978 [MARS], were taken account of. An administration of radioactive substances committee (ARSAC) certificate holder, the lead consultant based at the local acute trust and provided cover for the examinations they performed.

Incidents

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- There was an effective system in place for reporting incidents. Staff understood their responsibilities to raise concerns, to record safety incidents, concerns and near misses.
- There were no never events reported for the service from July 2017 to August 2018. Never events are serious incidents that are entirely preventable as guidance, or safety recommendations providing strong systemic protective barriers, are available at a national level, and should have been implemented by all healthcare providers.
- There were no serious incidents reported for the service from July 2017 to August 2018. Serious incidents are events in health care where there is potential for learning or the consequences are so significant that they warrant using additional resources to mount a comprehensive response.
- The service had recorded 23 incidents from October 2017 to July 2018. Nine incidents were graded as moderate risk, 14 were graded as low risk. Ten incidents were classified as the result of an operational issue for example as the result of procedural failure and appointment issues. Nine were clinical risks such as extravasation and medication issues. Two were safeguarding issues for example, patient came from the acute hospital without an escort or without food, drink and medication. Two incidents were the result of radiation protection issues such staff exposure to radiation. The service looked for opportunities to learn lessons from these incidents.
- Senior staff were aware of the requirements for reporting serious incidents to the CQC using the statutory notification route if this met the criteria, under Regulation 18 of the Care Quality Commission (Registration) Regulations 2009.
- We reviewed reported incidents. All incidents were recorded, reviewed and investigated with trends identified and actioned at a national and regional level. All serious incidents were reported within 24 hours and a root cause analysis (RCA) investigation undertaken. RCA investigation reports were reviewed at the relevant sub-committees who were responsible for making sure that appropriate remedial action and shared learning had taken place. During 2017 a new pathway for 'escalated events' was introduced to track incidents which the organisation considered require a more in-depth level of investigation to support prevention.
- From March 2015, all independent healthcare providers were required to comply with the Duty of Candour Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of 'certain notifiable safety incidents' and provide reasonable support to that person. Staff were aware of the duty of candour regulation (to be open and honest) ensuring patients received a timely apology when there had been a defined notifiable safety incident. The service had a duty of candour policy in place. The policy defined when the principles of duty of candour should be followed.

Safety Thermometer (or equivalent)

- The service did not complete the safety thermometer as this was not applicable to the service they provided their patients.

Are diagnostic imaging services effective?

We do not rate effective.

Evidence-based care and treatment

- In most cases, relevant and current evidence-based guidance, standards, best practice and legislation was used to identify and develop how services, care and treatment were delivered. However, we were not assured the standards of practice (SOP) available to staff on the intranet and in a folder to the office were up to date and referenced the Ionising Radiation Regulations 2017 (IRR17) and the Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R17). The SOP shown to inspectors referenced the 2000 regulations.
- Patients had their needs assessed and their care and treatment were planned and delivered in line with evidence-based guidance, standards and best practice. Relevant and current evidence-based guidance, standards, best practice and legislation identified and were used to develop how services, care and treatment were delivered for example, evidence-based indications for the use of PET-CT in the United Kingdom' (2016). However, we were not assured staff were aware of the

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Ionising Radiation Regulations 2017 (IRR17) and the Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R17). On the day of inspection, staff were initially unable to locate the document to show to inspectors.

- Policies procedures and staff competence ensured, in relation to diagnostic procedures involving nuclear medicines, the practitioner noted the diagnostic reference level for each adult investigation. Activity for each exposure was the optimised so it is the lowest practicable dose to the patient.
- All PET-CT reporters were included in the national programme audit schema. This was a randomised 10% surveillance audit undertaken by auditors independent to the reporting clinicians. For National Health Service Executive (NHSE) programme sites such as Northampton PET-CT Centre this was a centrally coordinated audit process. The results were held centrally, with feedback provided throughout the year to reporters to allow for reflection of practice.
- An audit of radiation protection arrangements was carried out at the service in June 2018 by the radiation protection adviser and radiation protection supervisor. The audit reviewed the service's departmental procedures, protocols and practices against the legislative requirements and associated guidance. The radiation employer for the centre was Alliance Medical Ltd (AML). The radiation protection adviser (RPA) and medical physics expert (MPE) are appointed under contract from the acute trust. The centre was operated and staffed by AML, including the unit manager who was appointed as the radiation protection supervisor (RPS). The audit reviewed several subjects, including
 - Changes from initiation IRR17:
 1. Radiation safety meeting
 2. Radiation protection policies
 3. Written QC procedures (IRR17 Reg. 33(3))
 4. Patient dose assessment (IRR17 Reg. 33(3) -(4))
 5. Staff dose
 6. Imaging protocols
 7. Patient dose assessment
 - One action from the audit was identified: The recommendations from the recent patient dose audit should be implemented:
 1. Patient dose audit recently completed following changes to the CT protocols.

2. Mean injected activity for F-18 FDG was 279 MBq (NDRL = 400 MBq).
3. Mean CTDIvol for a half-body PET-CT scan was 3.5 mGy (proposed NDRL = 4.3 mGy).

- There was evidence the recommendations had been completed.

Nutrition and hydration

- There were no nutrition services provided by the unit for patients that attended for PET-CT scans. However, patients had access to bottled water in reception and in the waiting/treatment rooms.

Pain relief

- Patients were asked by staff if they were comfortable during their appointment, however no formal pain level monitoring was undertaken as procedures undertaken were pain free.

Patient outcomes

- Information about the outcomes of patient's care and treatment was routinely collected and monitored. The service undertook regular clinical audits internally within the organisation. They took appropriate action to monitor and review the quality of the service and to effectively plan for the implementation of changes and improvements required.
- All PET CT reporters were included in the National Programme Audit scheme. A randomised 10% surveillance audit was undertaken by independent auditors. This was a centrally coordinated audit process. The results were held centrally, with feedback provided throughout the year to reporters to allow for reflection of practice.
- The time between when a referral to the service for a scan was received and that a scan being booked was recorded. Between August 2017 and July 2018 90.8% patients were seen within five days. 6.1% of patients were seen within five days 1% of routine patients were seen within six days. 0.8% of routine patients were seen within seven days and 1.2% of routine patients were seen over seven days. Reasons for delays included scanner breakdown, this resulted in one patient waiting more than ten days; administration processing error, this resulted in one patient waiting more than ten days and a problem getting isotope, this resulted in six patients waiting more than ten days. All delays were

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investigated, none had resulted in serious incident notification needing to be raised and actions had been taken to ensure actions to reduce future delays were taken and any lessons identified were learned. Delays in sourcing isotope have been addressed.

- The service manager audited and compared key elements of the referral and scanning pathway and these were benchmarked with other AML locations.
- Audits of the quality of the images were carried out by the acute trust. The services re-scanning rate was negligible
- The consultants from the acute trust were responsible for the reporting of images. This was monitored by NHS England.
- There was an audit schedule in place. The audits aimed to assist in monitoring the service and drive improvement. It involved all staff ensuring they had ownership of things that had gone well and that needed to be improved. Audits included incidents, complaints, hand hygiene, infection prevention and control and patient satisfaction.
- A monthly report was submitted to the commissioners, this provided the commissioners with information on activity and any issues impacting on service provision such, as staffing, equipment, operational issues and improvements.

Competent staff

- 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. The service operated a comprehensive mandatory and statutory training programme which ensured relevant knowledge and competence was maintained and updated throughout the lifespan of employment with the organisation.
- Staff had regular informal meetings with their manager and a performance appraisal annually to set goals to review them. At the time of inspection, all eligible staff had received an appraisal in the last 12 months.
- All eligible staff had had their professional registration checked in the last 12 months.
- All radiographers were HCPC registered and met the standards to ensure delivery of safe and effective services to patients. Clinical staff were required to

complete continued professional development (CPD) to meet their professional body requirements. All eligible staff had had revalidated their professional registrations in a timely manner.

- Key attributes to ensure staff suitability were assessed as part of the interview process which were based on predetermined questioning that aligned with the service's core values.
- In the event of any aspect of competency falling short of the required standard, the staff member's line manager was responsible for providing necessary support and guidance required to attain the relevant standard.
- Ongoing staff competence was managed through the performance review process, for example where local audit, complaints and incidents, that highlighted potential failing areas where different staff members may need support and development.
- Radiographers' scanning performance was monitored through peer review and issues were discussed in a supportive environment. Radiologists also fed back any perceived issues with scanning to enhance and learning or improvements in individual performance.
- There were clear records showing who was entitled to administer radioactive medicinal products (RMP) together with who has the necessary certificate from 'The Administration of Radioactive Substances Advisory Committee' (ARSAC).

Multidisciplinary working

- Staff were appropriately involved in assessing, planning and delivering patient's care and treatment. Staff worked closely with the referring NHS trusts, this ensured a smooth pathway for patients. Staff were aware of the days of the different cancer multidisciplinary meetings ran and endeavoured to ensure the results of short notice scans were available to be discussed when necessary.
- Staff working in the service had good relationships with external partners and undertook scans for local NHS providers. We saw good communication between services and there were opportunities for staff to contact refers for advice and support.

Seven-day services

- The service was not open seven days a week. It operated on Mondays, Wednesdays and Fridays but had the potential to increase the capacity when required.

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- The service had capacity for eight PET-CT fluorodeoxyglucose (FDG) scans on Mondays, and on Wednesdays. There was capacity for 17 PET-CT FDG and fluoroethylcholine (FEC) scans and capacity for eight PET-CT FDG scans on Fridays.

Health promotion

- Information leaflets such as understanding your PET-CT scan were sent to patients with their appointment letters and were available in the waiting rooms. These leaflets included information about what the scan would entail and what was expected of the patient before and after the scan appointment.
- Health promotion information leaflets and posters on subjects such as smoking cessation services and information on living with cancer were on display in the waiting rooms. In addition, there was a range of information leaflets for patients and relatives, including those from Macmillan and the Stroke Association which patients could take away.

Consent and Mental Capacity Act

- Staff understood the relevant consent and decision-making requirements of legislation and guidance, including the Mental Capacity Act 2005 and the Children Acts 1989 and 2004. Staff had received training on mental capacity.
- Staff were aware of what to do if they had concerns about a patient and their ability to consent to the scan. They were familiar with processes such as best interest decisions.
- There were no patients attending at the time of inspection, who lacked capacity to make decisions in relation to consenting to treatment. Staff told us if, for example, a patient with a learning disability or a person living with dementia was due to attend, they would be advised to attend with a relative or carer to provide the necessary support.
- Diagnostic imaging procedures were consented for appropriately. A corporate consent policy was available to staff, and it was written in line with national guidance. We reviewed four patient care records all included a consent to treatment record.
- We observed staff obtaining verbal consent from the patients during their interventions. Patients we spoke with confirmed their consent had been obtained throughout the scanning process.

- Scan safety consent forms were completed by all patients prior to their scan, to record the patients' consent. These also contained patient's answers to safety screening.

Are diagnostic imaging services caring?

Good 

We rated this service as **good**.

Compassionate care

- Staff understood and respected patient's personal, cultural, social and religious needs, and took these into account.
- Staff took the time, where possible, to interact with patients and those close to them in a respectful and considerate manner. Staff were encouraging, sensitive and supportive to patients and those close to them.
- Staff made sure that patients' privacy and dignity was respected, for example, blinds over the window between the control and scanning room were closed while the patient moved onto the scanning plinth. There was a toilet/changing area, where patients could change their clothing. Staff made patients aware of the close circuit television in the examination rooms, so they did not change in these rooms.
- Care observed met National Institute for Health and Care Excellence (NICE) QS15 Statement 1: 'Patients are treated with dignity, kindness, compassion, courtesy, respect, understanding and honesty', NICE QS15 Statement 2: 'Patients experience effective interactions with staff who have demonstrated competency in relevant communication skills', NICE QS15 Statement 3: 'Patients are introduced to all healthcare professionals involved in their care and are made aware of the roles and responsibilities of the members of the healthcare team' and NICE QS15 Statement 13: 'Patients' preferences for sharing information with their partner, family members and/or carers are established, respected and reviewed throughout their care'.
- We spoke with four patients and one relative, all said they had been very happy with the service they had received. One patient described the service as efficient and caring. No patients raised any concerns about their treatment. All said they had been treated with care, compassion and respect.

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- Every patient had the opportunity to complete the NHS Friends and Family Test (FFT) and indicate their likelihood to recommend the service. There was an opportunity to add free text comments on any positive or negative aspects. The FFT process used a paper-based form complete with website address so that patients may choose to complete it digitally on a personal device. The results were collated by an external provider and delivered to service managers. The service manager reviewed the results which summarised response rates (24% for this location between August 2017 and July 2018) and overall likelihood to recommend (currently 87%) and unlikely to recommend (currently 2%). When asked how satisfied they were with their overall experience, 71% said very satisfied, 20 said satisfied, 3% were not satisfied. When asked how satisfied they were with the booking process, 73% said they were very satisfied. The free text comments were interrogated to enable positive staff feedback and individuals could be praised where they noted for the quality of care delivered. Negative comments were scrutinised for opportunities to drive improvement in the service.
- Staff recognised when patients and their relatives needed additional support to help them understand and be involved in their care and enable them to access this. This included, for example, access to language interpreters, sign language interpreters, specialist advice or advocates.
- Staff made sure that patients and their relatives, were able to find further information or ask questions about their care and treatment. There was a range of leaflets available, for example, information about the scans and information about common health conditions.
- Relatives or carers were permitted to remain with the patient for their appointment if this was necessary.

Emotional support

- Staff understood the impact that a patient's care, treatment or condition had on their wellbeing and on their relatives, both emotionally and socially. Staff were aware patients attending the service were often feeling nervous and anxious. Staff provided reassurance and support and demonstrated calm and reassuring approach.
- A patient described how when they had told the staff how anxious they had been prior to attending, they had been spoken to with compassion and had ensured that they had information they required to lessen their concerns.
- Staff told us, if a patient became distressed, rather than provide support to them in an open environment, staff could take them in to a private room to talk to them, to assist them to maintain their privacy and dignity.

Understanding and involvement of patients and those close to them

- Staff communicated with patients to ensure that they understood their care, treatment and condition. Staff took the time to explain the procedure and what would happen during their appointment.

Are diagnostic imaging services responsive?

Good 

We rated this service as **good**

Service delivery to meet the needs of local people

- Information about the needs of the local population was used to inform how services were planned and delivered. The service provided PET-CT scanning for a local clinical commissioning group (CCG). The unit provided services through contractual agreements.
- Progress in delivering services against the contractual agreement was monitored by the, CCG. Monitoring was reported through monthly contract review meetings with the acute trust, and measurement of quality outcomes for example, the patient experience. Service improvements were agreed at these regular meetings.
- The service provided services for a range of patients. There was access to a hoist, for patients whose mobility required a hoist were referred to this service. However, at the time of inspection, the hoist was awaiting repair. Staff told us they could access an alternative hoist from a neighbouring department, if required, in the interim.
- Staff were confident and competent assisting patients who required assistance with their mobility.
- The service was accessible, it was on an established bus route. There was accessible car parking. Additional parking was available within a five-minute walk. However, parking costs were applicable for this parking.
- The facilities and premises were appropriate for the services that were planned and delivered. There was

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sufficient comfortable seating, toilets and a water fountain. Additional drinks and snack were available in the attached main hospital building. Each examination room was assessed for suitability prior to its use and provided privacy and dignity. There was sufficient space in each examination room for individuals accompanying the patient, for example, relatives or carers as well as patients.

- Information was provided to patients in accessible formats before appointments. Appointment letters containing information required by the patient such as contact details, a map and directions and information about the intervention including any preparation such as fasting was required. The appointments letters sent out, asked patients to call in if they had any queries or if they had answered yes to any of the questions on the safety questionnaire.
- All appointments were confirmed prior to patient's appointment, by phone. This helped reduce the number of do not attend (DNA's) and provided an opportunity for the patient to ask any questions they may have had. Should a patient not be verbally contacted prior to their appointment, for example where a message had been left for the patient on an answer machine, the patient was asked to call the service to confirm their intention to attend the appointment.

Meeting people's individual needs

- Patients' individual needs were accounted for. Staff delivered care in a way that took account of the needs of different patients on the grounds of age, disability, gender, race, religion or belief and sexual orientation. Staff had received training in equality and diversity and had a good understanding of cultural, social and religious needs of the patient and demonstrated these values in their work.
- Reasonable adjustments were made so disabled patients could access and use services on an equal basis to others. All patients were encouraged in the appointment letter, to contact the unit if they had any needs, concerns or questions about their examination.
- There was a system in place for managing the needs of patients living with dementia or learning disability. Staff making the referrals were able to add an alert which related to a patient's medical condition.
- Interpreters could be provided if the service was informed prior to the appointment. Staff also had

access to language line, a phone translation service where appropriate. In a clinical emergency. The service enabled staff to use a family member to translate at the radiographers' discretion.

- Staff provided patients with information leaflets and written information to explain the scan process.
- During the PET-CT scan, staff made patients comfortable with padding aids. Patients were given an emergency call buzzer to allow them to communicate with staff should they wish. Microphones were built into the scanner to enable two-way conversation between the radiographer and the patient. Patients could bring in their own music for relaxation.
- The service was based at an acute hospital and there were two cafés in waiting distance for patients who are there for any length of time.

Access and flow

- Patients had timely access to scanning. Since opening in August 2016, the service had worked closely with the acute trust team CCG; to improve the quality of the service provided. The service increased the PET-CT capacity available from two mobile service days to three service days at the static centre, with the objective of reducing the turnaround times for patients. The unit had the potential to increase the capacity if required.
- Referrals were prioritised by clinical urgency. If patient symptoms were deemed to be clinically urgent, these patients were often given an appointment within two days depending on the urgency.
- All patients on a two-week cancer pathway, were scanned within five days to enable swift report turn around. Where several clinically urgent requests were received, advice was sought from a radiologist on the priority order for booking. The unit kept one reserved slot on Monday, two on Wednesdays and one on Friday to accommodate patients on this pathway.
- Slots were not held for clinically urgent referrals, as they did not receive a significant number of these. Urgent referrals were offered the first available appointment, a two week wait slot could be used, if not needed for patients on the two-week wait pathways. There was an option for the patient to be scanned at Leicester PET/CT centre if capacity at Northampton was a problem.
- Should the need arise to add an urgent referral into the waiting list when no appointments were available, the unit manager would assess appointments filled by

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routine, not urgent examinations and rebook patients to make room for the clinical urgent case. The rebooked patient would be given the next available appointment to suit them.

- Thirteen planned procedures were cancelled for non-clinical reasons between August 2017 and July 2018, all were due to equipment failure, such as scanner break down.
- We saw one complaint from a patient that their planned procedures/examination was delayed for a non-clinical reason between August 2017 and December 2018. The 50-minute delay had been caused due to the late arrival of the fluorodeoxyglucose (FDG). The scan could not take place until the FDG was delivered.
- Appointments generally ran to time; reception staff would advise patients of any delays as they signed in. Staff would keep patients informed of any ongoing delays.
- Reporting on scans was carried out by the trust radiologists, the service did not report on reporting times. However, staff told us urgent scans were reported on within 24 hours. This met national guidance.

Learning from complaints and concerns

- Patients we spoke with told us they knew how to make a complaint or raise concerns about the service.
- A patients' guide to making comments, compliments and concerns was available in the corridor of the unit. Staff would also provide these to patients upon requested and/or when the local staff recognised its need.
- The service received three compliments and seven complaints between August 2017 and July 2018.
- All seven complaints were managed under the formal complaints process. However, none were upheld after investigation.
- Alliance Medical Ltd had a management of concerns and complaints' policy and procedure, all staff were obliged to acknowledge and comply with this process.
- The registered manager was responsible overseeing the management of complaints at the service. We saw evidence in the team meeting minutes, learning from complaint investigations were discussed and recorded.

Are diagnostic imaging services well-led?

We rated this service as **good**.

Leadership

- Leaders had the skills, knowledge, experience and integrity to manage the service. The service employed a part time, 0.5 whole time equivalent (WTE) unit manager, who was a radiographer. The manager also managed one other service, a diagnostic service based in Leicestershire. They were supported by a regional head of PET-CT molecular imaging services.
- The service manager was an experienced senior radiographer.
- The manager was knowledgeable in leading the service. They understood the challenges to quality and sustainability the service faced and had pro-active ongoing action plans in place to address them.
- The registered manager was fully aware of the scope and limitations of the service, based on the size, numbers and type of staff, and type of work booked for. All staff told us leaders were keen to keep developing the service to ensure the patients received a quality service.
- Staff we spoke with found the registered manager to be approachable, supportive, and effective in their role.

Vision and strategy

- The provider had a clear vision and a set of values, with quality and safety as the top priorities. The service's managing director described how as an organisation, they had a responsibility to continue to grow the services they provided, they had also invested in their teams, infrastructure and approach to quality to ensure they could continue to deliver on their key quality goals: 'The provision of safe, effective and timely services; ensuring measured, responsible outcomes from our services; and the provision of an experience that meets stakeholders' expectations.'
- Alliance Medical Ltd (AML) operated a collaborative approach to diagnostic imaging working with clinicians, local NHS providers and independent providers to keep the patient at the heart of their service. The collaborative approach to imaging services aimed to future proof the service, provide access to emerging

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clinical and technological developments and support research programmes, while supporting local pathways of care. The strategy was monitored through the clinical governance meeting and board meetings.

- The service values were:
 - ‘Collaboration: We work together and in partnership for all of our patients. We respect expertise and combine it to achieve more
 - Excellence: We never compromise. We strive to deliver the very best in everything we do to ensure the highest quality of care. We treat our patients and each other with compassion, dignity and respect.
 - Efficiency: Efficiency in healthcare means more patients get better care. We constantly seek new ways to use the scarce resource of healthcare more intelligently so that more people can live longer, fuller lives.
 - Learning: Knowledge and understanding comes from learning. At Alliance Medical we are committed to ensuring that each and every one of us keeps on learning and that we continuously look for improved ways of working.’
- Staff were aware and understood what the vision and values were and understood the strategy and their role in achieving it. Staff told us they were a major part in the way they worked. All staff were introduced to these core values at the corporate induction and then through their annual appraisal.

Culture

- The registered manager promoted a positive culture that supported and valued staff, creating a sense of common purpose based on shared values.
- The service’s culture was centred on the needs and experience of patients. This attitude was reflected in staff we spoke with on inspection.
- Equality and diversity was promoted, it was part of mandatory training, and inclusive, non-discriminatory practices were part of usual working.
- The provider had a whistle blowing policy and duty of candour policy which supported staff to be open and honest. The provider had appointed a freedom to speak up guardian. Staff were aware how they could raise concerns. Staff described the principles of duty of candour to us. Staff told us they attended duty of candour training.
- AML held an Investors in People award. The Investors in People award is the standard for people management.

The standard defined what it takes to lead, support and manage people for sustained success.” In March 2017, AML achieved reaccreditation for the new generation six standards, the process for which engaged a far wider range of employees through ‘quantitative’ data to support the qualitative data gathered during interviews at a later stage. A context meeting with senior managers explored the ambition of the organisation which would: ‘allow for people management practices to be assessed in line with our context and ambition as an organisation.’

- All independent healthcare organisations with NHS contracts worth £200,000 or more are contractually obliged to take part in the Workforce Race Equality Standard (WRES). Providers must collect, report, monitor and publish their WRES data and take action where needed to improve their workforce race equality. The provider had produced a WRES report in 2017. There was clear ownership of the WRES report within the provider management and governance arrangements, this included the WRES action plan reported to and considered by the board.

Governance

- There were governance frameworks to support the delivery of good quality care. The service undertook several quality audits, and information from these assisted in driving improvement and giving all staff ownership of things had gone well and action plans identified how to address things needed to be improved.
- Local governance processes were achieved through team meetings and local analysis of performance, discussion of local incidents. The service aimed to have team meetings on a monthly basis however on occasions, whole team meetings had to be postponed due to staffing or patient care needs. The manager would ensure necessary information was shared with staff if meeting were cancelled through email or one to one meetings.
- Feedback and actions from performance discussion of local incidents were fed into processes at a corporate level. We saw evidence of this process in meeting minutes and meeting notes during our inspection.
- Staff were clear about their roles and understood what they were accountable for. All clinical staff were professionally accountable for the service and care that was delivered within the unit.

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- Working arrangements with partners and third-party providers were managed. For example, there was a service level agreement between the service and the local acute trust. Monthly quality reports were issued, and regular meetings were held with the radiology services manager at the acute trust to discuss the service provided.
- The registered manager was the governance and quality monitoring lead for the service.
- There were processes in place to ensure staff were fit for practice, for example, they were competent and held appropriate indemnity insurance in accordance with The Health Care and Associated Professions (Indemnity Arrangements) Order 2014.
- Staff working with radiation were provided with training in the regulations, radiation risks, and use of radiation. However, it was not clear if staff were aware of the changes made by the introduction of the Ionising Radiation Regulations 2017 (IRR17) and the Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R17) which had been introduced in February 2018.

Managing risks, issues and performance

- There was a risk assessment system in place locally with a process of escalation onto the corporate risk register. The local risk register was reviewed and updated in May 2018.
- The local risk register included risks to patients and staff from equipment used, security of medicines, breach of privacy and dignity of patients. An action log was also included identifying timescales and accountability. However, we could not see that any new risks had been identified and added since May 2018.
- Performance was monitored on a local and corporate level. Performance dashboards and reports were produced which enabled comparisons and benchmarking against other services. Information on turnaround times, 'did not attend rates', patient engagement scores, incidents, complaints, mandatory training levels amongst others were monitored.

Managing information

- Electronic patient records were kept secure to prevent unauthorised access to data however, authorised staff demonstrated they could be easily accessed when required.

- The service was aware of the requirements of managing a patient's personal information in accordance with relevant legislation and regulations. General Data Protection Regulations (GDPR) had been reviewed to ensure the service was operating within the regulations. Staff viewed breaches of patient personal information as a serious incident and would therefore manage this as a serious incident and escalate to the appropriate bodies.
- Staff had access to AML policies and resource material through the internal computer system. However, Staff were not always able to locate and access relevant and key records easily, this enabled them to carry out their day to day roles. On the day of inspection, we were not assured staff were aware of the Ionising Radiation Regulations 2017 (IRR17) and the Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R17). On the day of inspection, staff were initially unable to locate the document to show to inspectors. Following a telephone conversation with a regional manager we were directed to the regulations, radiation risks, and use of radiation documents stored on the intranet.
- There were sufficient computers available to enable staff to access the system when they needed to.

Engagement

- Patients' views and experiences were gathered and used to shape and improve the services and culture. Patient surveys were in use, the questions were sufficiently open ended to allow patients to express themselves. We saw changes were implemented following feedback from patients. The response rate was 24% for the service between August 2017 and July 2018
- There was regular engagement with commissioners to understand the service they required and how they could be improved. This produced an effective pathway for patients. The service had a good relationship with local NHS trust.
- AML launched a high-performance initiative under the title, 'Getting Better Every day' in 2017. An in-depth diagnostic review was undertaken following this to deliver against five workstreams: Strategy, Structure, Workforce, Process and Technology. All employees were invited to participate in the workstream design and delivery. Employee engagement was also measured through an annual employee survey which was

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conducted by an independent organisation to ensure confidentiality. In response to the survey, action plans were developed and progress against the plans was measured on a regular basis.

- The service had a good relationship with local NHS trust. The service engaged regularly with staff at the acute trust to discuss the service provided.

Learning, continuous improvement and innovation

- Staff could provide examples of improvements and changes made to processes based on patient feedback,

incidents and staff suggestion. For example, following an incident where a patient with recognised difficult veins, during the Radiotracer administration their vein collapsed. Following investigation and advice sought, a new practice was introduced for patients with noted difficult veins or that had previous Radiotherapy and/or Chemotherapy. The administration of the radiotracer was done with a bolus as low as practicable to avoid venous collapse.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider SHOULD take to improve

- The service should ensure staff and patients are made aware of the changes required following the introduction of the Ionising Radiation Regulations 2017 (IRR17) and the Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R17) which were introduced in February 2018.
- The service should ensure staff the local rules and standards of practice (SOP) are up to date and reflect IRR17 IR(ME)R17.
- When administering fluorodeoxyglucose (FDG) to patients. The service should review the opportunity for a second clinician to check the dosage prior to administering. While there were checks when the radiopharmaceutical was dispensed, drawn up and level of radioactivity measured, a final four or five-way check immediately prior to injection of patient verses, demographics, verses intended exam, verses radioactive medicinal products (RMP) identity verses RMP activity, would be a useful 'fail-safe'.