Spire Southampton Hospital

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 summary

Spire Southampton Hospital is operated by Spire Healthcare Limited. The hospital was registered with the Care Quality Commission in 2010. The hospital offers outpatient, diagnostic imaging, inpatient medical and surgical care for adults, children and young people. The hospital also provides more complex care including specialist cardiac and spinal surgery, which is supported by an on-site critical care unit. Services are available for insured and self-funding patients, as well as working in partnership with local NHS trusts to provide NHS funded care.

The hospital has 60 inpatient rooms, a six-bedded children's suite, nine day care bays and seven critical care beds. There are four laminar flow theatres, an endoscopy suite and cardiac catheter suite. The outpatient department consists of 16 consulting rooms, two treatment rooms and a minor procedure theatre. The hospital hosts a computerised tomography (CT) room, magnetic resonance imaging (MRI) suite, x-ray room, digital mammography and a fluoroscopy suite.

The Spire Southampton Hospital provides surgery, medical care, services for children and young people, and outpatients and diagnostic imaging. This inspection was solely focussed on the diagnostic imaging core service.

We inspected this service using our comprehensive inspection methodology. We carried out an unannounced inspection on 23 April 2019.

To get to the heart of patients' experiences of care and treatment, we ask the same five questions of all services:

Summary of findings

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.

Services we rate

Whilst we have the legal authority to rate diagnostic imaging services, we have opted not to rate the service as a result of this inspection. This is due to there being a legacy rating for the wider outpatient and diagnostic imaging service. Because this was an unannounced inspection which focussed on one core service only, we have not inspected the outpatient core-service, and so legacy ratings remain in force.

Our key findings were:

- Governance processes surrounding the maintenance of personal protective equipment was not effective.
- Staff did not consistently follow provider and local level safety rules associated with the use and exposure of ionising radiation (X-rays).
- The service could not demonstrate they consistently provided care and treatment based on national guidance and evidence of its effectiveness.
- Managers did not routinely monitor the effectiveness of care and treatment and therefore could not use the findings to improve them. The lack of local level data meant it was not possible for the service to compare local results with those of other services to learn from them.
- Managers at all levels in the service did not have the right skills and abilities to run a service providing high-quality sustainable care.
- The service did not have a local vision for what it wanted to achieve.
- Morale was reported to be low with limited mutual respect shown between front-line staff and their managers. There did not exist a positive culture which should have supported and valued staff, creating a sense of common purpose based on shared values.
- The service failed to systematically improve service quality and safeguard high standards of care due to a lack of a culture which encouraged excellent clinical care to flourish.
- The service had poor systems to identify risks, plan to eliminate or reduce them, and cope with both the expected and unexpected.

However,

- The service provided mandatory training in key skills to all staff and made sure everyone completed it.
- Staff understood how to protect patients from abuse however the local policy was in need of updating to reflect recent updates to safeguarding concerns.
- The service controlled infection risk well. Staff kept themselves, equipment and the premises clean. They used control measures to prevent the spread of infection.
- The service had enough staff with the right qualifications, skills, training and experience to keep people safe from avoidable harm and to provide the right care and treatment.
- The service followed best practice when prescribing, giving, recording and storing medicines. Patients received the right medication at the right dose at the right time.
- Emergency equipment was available and regularly checked.
- Staff recognised incidents and reported them appropriately and managers investigated incidents and shared lessons learned with the whole team and the wider service. There was evidence of audits being completed to ensure that identified actions have been followed by relevant 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 monitor the effectiveness of the service.
- Staff understood how and when to assess whether a patient had the capacity to make decisions about their care. They followed the service policy and procedures when a patient could not give consent.
- Staff cared for patients with compassion. Feedback from patients confirmed that staff treated them well and with kindness.
- Staff provided emotional support to patients to minimise their distress.

Summary of findings

- Staff involved patients and those close to them in decisions about their care and treatment.
- The service planned and provided services in a way that met the needs of local people.
- The service took account of patients' individual needs.
- Staff could not describe a departmental vision or strategy. The provider subsequently reported that individual specialties were not required to have a local strategy, often due to the size of locations; it was acknowledged that each location had a hospital wide vision and strategy. Staff could describe the vision for the hospital. They also described the wider values of Spire Healthcare.
- People could access the service when they needed it. Waiting times from referral to treatment and arrangements to admit, treat and discharge patients were in line with good practice.
- The service treated concerns and complaints seriously, investigated them and learned lessons from the results, and shared these with all staff.

Following this inspection, we told the provider that it must take some actions. Details are at the end of the report.

Nigel Acheson

Deputy Chief Inspector of Hospitals (South)

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging		• Governance processes surrounding the maintenance of personal protective equipment was not effective. • Staff did not consistently follow provider and local level safety rules associated with the use and exposure of ionising radiation (X-rays). • The service could not demonstrate they consistently provided care and treatment based on national guidance and evidence of its effectiveness. • Managers did not routinely monitor the effectiveness of care and treatment and therefore could not use the findings to improve them. The lack of local level data meant it was not possible for the service to compare local results with those of other services to learn from them. • Managers in the service did not have the right skills and abilities to run a service providing high-quality sustainable care. • Morale was reported to be low with limited mutual respect shown between front-line staff and their managers. There did not exist a positive culture which should have supported and valued staff, creating a sense of common purpose based on shared values. • The service failed to systematically improve service quality and safeguard high standards of care by creating a culture which allowed excellent clinical care to flourish. • The service had poor systems to identify risks, plan to eliminate or reduce them, and cope with both the expected and unexpected. However, • The service provided mandatory training in key skills to all staff and made sure everyone completed it. • Staff understood how to protect patients from abuse however the local policy needed updating to reflect recent updates to safeguarding concerns.

Summary of findings

- The service controlled infection risk well. Staff kept equipment and the premises clean. They used control measures to prevent the spread of infection.
- The service had enough staff with the right qualifications, skills, training and experience to keep people safe from avoidable harm and to provide the right care and treatment.
- The service followed best practice when prescribing, giving, recording and storing medicines. Patients received the right medication at the right dose at the right time.
- Emergency equipment was available and regularly checked.
- 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 monitor the effectiveness of the service.
- Staff understood how and when to assess whether a patient had the capacity to make decisions about their care. They followed the service policy and procedures when a patient could not give consent.
- Staff cared for patients with compassion. Feedback from patients confirmed that staff treated them well and with kindness.
- Staff provided emotional support to patients to minimise their distress.
- Staff involved patients and those close to them in decisions about their care and treatment.
- The service planned and provided services in a way that met the needs of local people.
- The service took account of patients' individual needs.
- People could access the service when they needed it. Waiting times from referral to treatment and arrangements to admit, treat and discharge patients were in line with good practice.
- The service treated concerns and complaints seriously, investigated them and learned lessons from the results, and shared these with all staff.

Summary of findings

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Summary of this inspection

Background to Spire Southampton Hospital

Spire Southampton Hospital is operated by Spire Healthcare Limited. The hospital was first registered with the Care Quality Commission in 2010. It is a private hospital located near to Southampton town centre in Hampshire. The hospital primarily serves the communities of the Southampton and South Hampshire. It also accepts patient referrals from outside this area.

The hospital has had a registered manager in post since first registering with CQC in 2010. The current registered manager has been in post since 2017.

Our inspection team

The team that inspected the service comprised a CQC lead inspector and a specialist advisor with expertise in radiology services. The inspection team was overseen by Amanda Williams, Interim Head of Hospital Inspection.

Information about Spire Southampton Hospital

The hospital is registered to provide the following regulated activities:

- Treatment of disease, disorder or injury
- Surgical procedures
- Diagnostic and screening procedures
- Management of supply of blood and blood derived products.

During the inspection, we visited the diagnostic imaging suite and cardiac catheter suite. We spoke with fourteen staff including registered radiographers, nurses, reception staff, medical staff and senior managers. We spoke with four patients. During our inspection, we reviewed eight sets of patient records including imaging requests forms.

There were no special reviews or investigations of the hospital ongoing by the CQC at any time during the 12 months before this inspection. The hospital has been inspected four times, and the most recent inspection took place in October 2016 at which time the hospital was rated good overall. The outpatient and diagnostic imaging service was rated good for safe, caring, responsive and well-led. Effective was not rated as our inspection methodology was such that we were not collecting sufficient evidence to enable us to rate the service.

Diagnostic imaging

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are diagnostic imaging services safe?

Mandatory training

- Within Spire Healthcare, the mandatory training cycle ran from 1 January to 31 December each year. Modules included within the annual mandatory training programme included information governance, health and safety, fire safety and infection control. A range of supplementary modules were also included in the annual programme including but not limited to compassion in practice and equality and diversity.
- Compliance against each of the mandatory training modules for 2018 for diagnostic imaging services was as follows:
  - Information governance 86%
  - Anti-bribery 94%
  - Fire Safety 97%
  - Health and safety 97%
  - Infection control 97%
  - Manual handling 97%
  - Compassion in practice 97%
  - Equality and diversity 100%
- At the time of the inspection, compliance against mandatory training modules for 2019 was:
  - Health and safety 80%
  - Infection control 80%
  - Fire Safety 88%
  - Manual handling 93%
  - Information governance 93%
  - Compassion in practice 100%
  - Equality and diversity 100%
  - Anti-bribery 100%

(Source: D14)

Safeguarding

- Spire Healthcare provided staff across all professions with relevant training in safeguarding both adults and children. Staff were familiar with the different categories of abuse and could describe the action they would take should they identify any concerns with a patient, visitor or other staff member.
- Ninety six percent of radiographers had completed levels one, two and three child safeguarding training and level one and two adult safeguarding at the time of the inspection. In addition, all radiography assistants and administration staff (100%) had completed safeguarding training level one and two for both adults and children. (Source: D14)
- Staff could direct us to both the child and adult safeguarding policies. The provider submitted the local Spire Southampton child safeguarding policy as part of a formal data request made by CQC following the inspection. This had last been updated in 2016; we noted that named professionals within the policy no longer worked at Spire Southampton Hospital, for example the hospital director. In addition, whilst the safeguarding policy referred to information sharing and some of the regulations associated with such activities, including the data protection act, there was no reference to the General Data Protection Regulations which came in to force in 2018. Whilst the children's safeguarding policy referred to the most common types of abuse including neglect, physical abuse, sexual abuse and emotional abuse, there was no information relating to other types of concerns including the radicalisation of young people, female genital mutilation or child sexual exploitation (Source: D13). The provider subsequently informed us that staff could also access the wider Spire's national safeguarding policy which referenced the above forms of abuse and regulations which were absent from the local policy.

- Information was displayed around the department which prompted patients to request a chaperone should they require one.

Cleanliness, infection control and hygiene

- Ninety seven percent of staff working in the diagnostic imaging service had completed infection prevention control and hygiene training during 2018 (Source: D14).
- Staff were observed to be bare below the elbow.
- The department and imaging suites were visibly clean.
- There were arrangements in place for ensuring clinical and domestic waste was appropriately segregated and disposed of in accordance with statutory requirements. There were colour coded bins throughout the department. Sharps bins were not overfilled, were securely fastened to walls, or out of reach of young children.
- Daily infection prevention and control audits were carried out across the diagnostic imaging suite. Audit results demonstrated consistent 100% compliance across the six clinical areas including x-ray, CT, MRI, mammography and the fluoroscopy suite. (Source D08)
- The provider submitted examples of hand hygiene competency assessments which had been completed for two members of staff. The assessments captured the five motions of hand washing as described by the World Health Organisation. In addition, the competency framework sought to consider the theory and importance of health professionals undertaking appropriate and effective hand hygiene in a clinical setting.
- A quarterly jewellery and uniform audit was undertaken in April 2019 which demonstrated staff in the diagnostic imaging service were 100% compliant with Spire's uniform policy. This was consistent with our observations during the inspection. (Source D08).

Environment and equipment

- Most of imaging equipment had been in situ for a period of approximately nine years. This meant equipment including the fluoroscopy imaging machine and magnetic resonance imaging scanner were nearing the end of their ten-year life-span. The hospital director reported that whilst they had submitted a business case for the replacement of the MRI scanner, they had yet to receive confirmation from Spire Healthcare head office as to whether this had been approved or not. The provider did however have a range of contingency plans in place should any imaging equipment fail. This included local arrangements with other independent health providers to refer patients for imaging in the event of mechanical failure. Service level agreements existed with machine manufacturers to enable the timely repair of all imaging equipment in the hospital.
- The provider had a process in place for the annual checking of personal protective equipment including lead aprons and thyroid shields. These checks were included in the Local Radiation Protection Local Rules Protocol. The imaging department had recently devised a quality scorecard which consisted of a range of safety metrics including radiation quality assurance processes. Radiation protection equipment was listed as one such safety metric. The measure as to whether the service met this specific metric was determined by whether lead coat checks had been completed. The scorecard for April 2019 reported that checks were completed for January and February 2019. Further checks were scheduled for August 2019. However, whilst the scorecard metric for lead protection equipment was rated as green (complete), a review of audit documents submitted by the provider suggested that some radiation protection equipment including lead aprons, had not been checked and cleaned since September 2017. This meant there was a risk staff and patients were using personal protective equipment which may not be fit for purpose due to wear and tear.
- The local radiation protection rules also required staff to ensure that when not in use, lead aprons were hung on the hangers provided. During the inspection we noted a range of lead aprons which were poorly stored, including be hung over the apron stand, contrary to the requirements of the local rules.
- Whilst the provider's local rules protocol reported that staff working in the fluoroscopy or cardiac catheter suite or those undertaking interventional radiology procedures were required to wear a second dosimeter at collar level, staff we spoke with in the fluoroscopy suite were unaware of this requirement. This suggested limited insight amongst local staff as to the requirements set-out in the local ionising radiation (medical exposure) regulations local rules. Because of the lack of knowledge among staff working in the fluoroscopy suite, regarding the wearing of a collar based dosimeter, the provider could not fully satisfy themselves that local rules were consistently being met. Further, staff working in the fluoroscopy suite were

unaware of the requirement for there to be monitoring of eye doses of ionising radiation (as set out in the Ionising Radiation (Medical Exposure) Regulations 2017 in cases where collar dosimeter readings suggested increased exposure over a given time.

- The x-ray room was visibly clean and tidy and patient safety information was clearly on display. This included the Royal College of Radiology "Pause and Check" protocol; national diagnostic reference levels; instructions for calling for help in an emergency and local rules. X-ray warning boxes were located outside those rooms in which x-rays were taken. Access to the MRI and CT suite was controlled by way of a locked door.
- Staff undertook safety checklists of all patients and visitors who required access to the MRI suite. We noted that a trolley and wheelchair was marked as safe for use in the MRI suite. However, we observed an oxygen cylinder located near the MRI suite which was not clearly labelled, and so presented as a possible significant risk should the cylinder inadvertently be taken in to the MR room itself.
- Regular checks of the MR, CT and x-ray devices was undertaken annually by the radiation protection advisor (RPA) service. The MR had last been tested on 11 September 2018 with the quality assurance checks reported as satisfactory, with the scanner operating safely and within tolerances. The mammography machine was tested in October 2018 and again was marked as satisfactory. The CT scanner was tested on 10 September 2018, with all criteria met. An advisory note was made requiring the service to update their local rules in order they were consistent with the updated IR(ME)R 2017 regulations.
- The clinical effectiveness group met monthly and considered any national alerts relating to medical devices or equipment used within the service. It was noted the diagnostic imaging manager had not attended either of the previous two meetings. Therefore, it was unclear how the diagnostic imaging manager engaged in the clinical effectiveness process, and how radiology services were assessed or considered.
- The Radiation Protection Advisory Service had undertaken a review of the diagnostic imaging service on 20 February 2019. The findings of the report concluded "Good compliance with the regulations and associated guidance was found. Except where indicated recommended actions from the previous review January 2018 have been completed. Points of non-compliance and associated recommended actions (including opportunities for improvement)". Within the report, it was confirmed that there was a process in place for inducting and assessing the competency of those individuals working within the diagnostic imaging setting and that there were training records for practitioners and operators. The IR(ME)R 2017 regulations require providers to maintain competency assessments registers which confirm that those staff working on machines which release ionising radiation are suitably competent. The local diagnostic imaging manger reported that whilst there was a register for radiographers, which we reviewed at the time of the inspection, there had been no formal competency assessments completed for radiologists working in the department who used the x-ray machines. We further noted that the RPA had failed to recognise that staff working in the fluoroscopy suite did not routinely wear a collar dosimeter as was required by the local rules; commentary was only made of those working in the cardiac catheter suite. Our third observation was the RPA had reported that annual checks of lead aprons had been carried out; this was despite local audit logs suggesting some aprons had not been checked for more than one year. This meant the overall assessment within the radiation protection advisors report was inaccurate and therefore provided a level of false assurance to those who had commissioned the report.
- Resuscitation equipment was located in the department. There was evidence that regular checks of the trolley occurred.

Assessing and responding to patient risk

- MRI patient safety questionnaires were completed by the patient before scanning took place. Completed forms were checked by the radiographers prior to the patient being allowed access to the MR/CT suite. Other individuals who also required entry to the MR suite were also screened to ensure they were not at risk of harm caused by the strong MR magnet.
- The pregnancy status of women was routinely checked and there was evidence of such checks being conducted. However, we spoke with four radiographers during the inspection. They were unable to describe the action they would take should a patient have a confirmed pregnancy. Staff could not direct us to any standard operating procedure detailing the most appropriate course of action, with the response

provided that "We do not really get any pregnant woman here". We subsequently reviewed the local rules for the service which clearly detailed the action staff should take should a pregnant woman be referred for imaging. This again suggested a lack of understanding and insight in to the providers radiation protection local rules and IR(ME)R employer's procedures, among radiographers working in the service.

- The diagnostic imaging manager reported there had been no emergency evacuation scenario training within the CT or MRI suite during their time as the department manager. The hospital director was not aware of any planned scenario training. Staff reported they would transfer any patient who became unresponsive from the scanner, to the recovery area located in the MR/CT suite. However, because staff had not rehearsed this procedure, there was a risk that staff may not have been sufficiently proficient in undertaking an effective and safe transfer.
- In 2018, a patient underwent an interventional radiology procedure to the wrong part of their body, resulting in the provider submitting a Never Event incident to local NHS commissioners. As a result of the incident, a root cause analysis was undertaken and a range of actions had been implemented to reduce the risk of future incidents from occurring again in the future. This included a review of the existing surgical safety checklist used in the interventional radiology suite. Supplementary actions included ensuring that previous relevant images were displayed prior to the commencement of any interventional radiology procedure. Information submitted to the Care Quality Commission in December 2018 stated that regular audits of the above actions would be implemented as a means of providing the hospital director with the necessary assurances that staff were following changes to practice. Audits of the radiology safety checklist were completed for January, February and March 2019, in which compliance was recorded as 100%. Data submitted by the provider confirmed that as part of the audit process, checks were also made to confirm that where applicable, consultant radiologists confirmed they had reviewed any available images prior to undertaking any interventional radiology procedure.

Allied Health Professional staffing

- The department was led by a diagnostic imaging manager who had been in post since July 2018 but was subsequently leaving two weeks after the date of our inspection. The department had a total radiographer establishment of 14 whole time equivalent staff. The manager reported there had been significant attrition of staff within the x-ray modality but that this has since improved since their arrival in July 2018 with the completion of a successful recruitment campaign. At the time of the inspection, there was one vacancy for an x-ray radiographer and 2 vacancies for the MR/CT modalities.
- A generic staffing risk assessment tool was in place, and staffing was mapped and planned against planned activity to meet the needs of the service. The MR and CT suite were both supported by two radiographers to each modality at all times. Staffing of the x-ray and fluoroscopy modalities was flexible depending on service demand.

Medical staffing

- At the time of the inspection, 33 consultant radiologists had practising privileges at Spire Southampton Hospital. The provider reported that during the preceding 12 months, there had been no instances in which a radiologist had their practicing privileges revoked or suspended.

Records

- In 2018 the provider informed the Care Quality Commission of an incident in which approximately 1,300 requested imaging examinations had been completed but had not been reported. Whilst we requested the root cause analysis for the incident, the provider reported that the final version of the report would not be available until 31 May 2019, some four months after the initial incident was reported to us. However, anecdotally, the Hospital Director reported that approximately 50% of the 1,300 images had been reported but the reports had not migrated from one computer system to another. In another 25% of cases, whilst there was no formal radiological report, the images were request from referrers who would routinely report their own images (for example, in the case of orthopaedic consultants who routinely reported musculo-skeletal films). In the remaining 25% of unreported images, there had been no report. Following the inspection, the provider reported that the backlog had been cleared and a harm review had taken place to determine whether any patient had come to harm as a

result of their image not being reported. Whilst we have not received the final root cause analysis, the provider gave us verbal assurances that no patients had experienced harm. As a means of mitigating against similar incidents occurring again in the future, the diagnostic imaging manager reported that weekly audits were now carried out on the radiological information system to ensure that all requested images had been reported. We asked for evidence that these checks had been, and continued to be, carried out but the provider was unable to submit any due to it not existing. We could therefore not be assured that sufficient mechanisms existed to prevent similar incidents from occurring again in the future, and subsequently raised this with the provider on conclusion of the unannounced inspection visit on 23 April 2019. The provider reported that whilst they could demonstrate that checks were being carried out, there had been no formal audit process. A new process had since been established however we have not yet returned to assess the impact of this new process,

Medicines

- Medicines were stored in locked cupboards. Room temperatures in which medicines were stored were checked daily. We noted one fridge located in the MR/CT suite which contained point of care testing and calibration solutions was unlocked with a temperature of 21^{0}C, significantly higher than the expected range of between 2^{0}C and 8^{0}C. We raised this with the diagnostic imaging manager at the time of the inspection.
- Radiographers used a range of patient group directives (PGDs) to enable them to administer a range of medicines including contrast studies, during CT and MR scans. A patient group direction is a written instruction for the supply or administration of a licensed medicine (or medicines) in an identified clinical situation, where the patient may, or may not, be individually identified before presenting for treatment. Copies of patient group directions were stored locally. We reviewed a range of PGDs and noted they were signed by practitioners and the authorising manager; associated competency documents were available for review and all PGDs were in date and valid for use.

Incidents

- There was an electronic system for the recording of incidents and outcomes were discussed at staff meetings. All staff, including temporary workers and consultants could access the incident reporting system.
- Between 21 May 2018 and 7 March 2019 staff reported 85 incidents relating to imaging services. 22 reports were associated with incidents which resulted in low harm; 1 incident resulted in moderate harm and 62 incidents resulted in no harm or were classed as a near miss. At the time of the inspection, five incidents remained open and were subject to investigation (Source D15).
- Between May 2018 and March 2019, the service reported one Never Event. This related to a procedure being carried out on the wrong part of the body. There was evidence the Never Event had been discussed at the Medical Advisory Committee in December 2018. The investigation in to the events which contributed to the Never Event identified that a lack of formalised consultant induction had been identified as one contributory factor. This was to be addressed through the commencement of a formal consultant induction programme which was scheduled to commence in 2019. The completion of one imaging request form per procedure was also re-iterated to those attending the Medical Advisory Committee (Source: D09). In addition, an updated surgical safety checklist was instigated, referred to locally as the WHO checklist (World Health Organisation). We asked staff whether any local or national safety standards for invasive procedures (LocSIPPs & NatSIPPs) existed. We were informed that no such document or procedure existed; this was despite there being a WHO checklist in place for radiology procedures and a national LocSIPPs across Spire Healthcare through a national policy.

Are diagnostic imaging services effective?

Evidence-based care and treatment

- The service relied on national diagnostic reference levels (DRLs) for each piece of scanning equipment that produced radiation. DRLs are used as a guide to help promote improvements in radiation protection practice. They can help to identify issues relating to equipment or practice by highlighting unusually high radiation doses. At the time of the inspection, the service did not have a baseline set of locally derived diagnostic reference

levels. This was consistent with the Spire Healthcare clinical guideline 19 document which referenced the national DRLs as the recommended guide. The service was in the process of collating a local DRL dataset to enable them to have a locally defined set of information which could be used as a benchmark for future procedures.

- There was a process in place for ensuring that all magnetic resonance imaging (MRI) and computer tomography scans (CT) were "Protocoled" by a consultant radiologist. Protocols are a pre-defined set of imaging sequences which have been designed to optimally assess a specific region or regions of the body. This ensured that patients referred for CT or MR scans were afforded the most appropriate sequence of scans available, whilst also minimalising the total exposure of ionising radiation for those undergoing CT scans.
- Whilst staff could describe the "Irefer" tool, they reported very restricted access to the online tool and therefore the use of Irefer was limited. Irefer was developed in conjunction with the Royal College of Radiologists and was recognised as a resource which provided clinical guidelines, supported decision making processes for those responsible for justifying examinations under the ionising radiation (medical exposure) regulations (IR(ME)R) 2017.

Pain relief

- Patients attending for interventional radiological procedures including joint injections were offered oral pain relief on an individual basis. Patients were provided with contact information for the hospital in the event they experienced pain which could not be controlled with regular analgesia. There was no local audit activity to demonstrate how well the service managed patient's pain post-procedure. It was therefore not possible for us to explore the full extent of this key line of enquiry.

Patient outcomes

- Quality assurance and audit processes across the diagnostic imaging department were varied, with some activity being sporadic and inconsistent. Staff reported a turnover of senior staff and the absence of a substantive manager for a period of approximately eighteen months prior to the current post holder taking up post had led to a hiatus in the completion of the quality assurance programme across the service. A clinical service review of the diagnostic imaging department was undertaken by representatives from Spire Healthcare head office on 24 January 2019. Findings of the report concluded that the quality assurance of radiology equipment required urgent updates. A recommendation was made in the report for staff to commence weekly checking of equipment to establish a baseline set of results. At the time of the inspection, weekly quality assurance remained inconsistent. Staff reported a lack of time and competence as reasons for quality assurance checks only be completed by a small number of staff who were often deployed to provide patient care, and therefore not able to complete quality assurance checks. The diagnostic imaging manager acknowledged the need to significantly improve the process, however they could not detail the action they were taking to address the issue. A report issued by the providers radiation protection advisory service in May 2018 advised that two mobile image intensifiers were producing higher dose rates of ionising radiation than expected. In one case, one intensifier was producing more than 50% the expected dose. The discrepancy was only recognised by an external engineer who was replacing the computer on one of the intensifiers. Whilst action was taken to address the discrepancy, there was an action for the service to recommence local quality control checks of both devices as these had discontinued. The lack of quality control meant patients had potentially been exposed to higher doses of ionising radiation than may have been necessary, and for an unknown period of time.
- There was no formalised discrepancy reporting process within the service. The Royal College of Radiologists recognises discrepancy reporting processes as a means by which services can learn collectively from radiology discrepancies and errors and therefore improve patient safety.

Competent staff

- Since the arrival of the current diagnostic imaging manager, a register of competencies for radiographers had been established, in accordance with IR(ME)R 2017 requirements. Whilst the manager had developed a register for radiologists, there was no record of any consultant radiologist having undertaken any competency assessment to demonstrate they were safe to use the x-ray modality equipment in the department. This was contrary to the IR(ME)R 2017 regulatory requirements. We raised this with the hospital director

on conclusion of the inspection who informed us the issue would be addressed in a timely way. Following the inspection, the provider submitted information which set out the action that was being taken to ensure this area was addressed with the consultant radiologist workforce.

- There was a framework in place for supporting radiographers to develop competency and experience in the use of supplementary modalities including computer tomography and magnetic resonance imaging. Evidence of this was seen during the inspection.
- Radiographers reported having received an appraisal from their line manager or senior radiographer during the preceding twelve months. Records of these were reviewed during the inspection. Appraisals detailed development opportunities for health professionals. Staff reported opportunities for personal and professional development including undertaking post-graduate qualifications.

Multidisciplinary working

- The imaging service was represented at the daily MDT safety huddle. In addition, every patient undergoing any form of surgical or medical treatment for cancer following a diagnosis must be discussed at an MDT. The hospital had a service level agreement in place for access to such meetings at the local NHS trust. Compliance with this was monitored monthly and reported quarterly via Spire's clinical scorecard with hospital compliance for Q1 2019 at 100%. Attendance at these meetings included the oncologist or surgeon and the Radiologist.

Seven-day services

- There was no formalised radiologist on-call rota to support the service. Two surgeons reported they could contact radiologist colleagues out of hours in the event they required an urgent report completed. The lack of formal rota was identified during the clinical service review in January 2019 however no action had been taken to engage with the consultant body for such a service to be offered. Staff reported the number of sub-speciality radiologists meant that a generic on-call rota would have proved challenging to support.
- The main diagnostic imaging department was open Monday to Saturday. Radiographers were on-call out of hours to support urgent requests for imaging within the in-patient setting.

Consent and Mental Capacity Act

- Where patients did not have the capacity to consent to a scan or other imaging procedure, the provider would risk assess on a case-by-case basis. The provider could describe the best interest and legislative practices where such a patient would be scanned.
- Radiographers were required to screen and approve MR and CT contrast questionnaires prior to any scan being undertaken. These forms also served as a consent form and detailed the procedure and any likely risks associated with the intended scan.
- A review of the 2018 never event suggested consenting processes for interventional procedures had not always been consistent with national best practice. The consultant involved in the incident reported that whilst they had gained verbal consent for the procedure, there was no documented evidence of written consent. Actions had been identified including the need for consultants to obtain written consent before any interventional radiology procedure was carried out. A monthly audit had been put in place to monitor that written consent was in place for all patients.

Are diagnostic imaging services caring?

Compassionate care

- We observed staff introduce themselves to patients prior to their scan. Staff wore name badges which were visible and clear.
- The environment had been adapted to ensure patients privacy and dignity was maintained; this included individual changing rooms for those patients attending for MR and CT scans for example.
- We spoke with four patients who told us they found the staff to be caring and kind. Each patient said they would recommend the service and they would use it again.

Emotional support

- Staff were able to spend time with patients to explain their intended procedure or scan. Where patients were claustrophobic (a phobia of enclosed spaces), patients were counselled and could spend time adjusting to being in the MR scanner before the scan commenced.
- Staff could communicate directly with patients when they were undergoing MR scans by way of an intercom. Staff could provide reassurance to patients as well as provide updates on the duration of scans.
- Chaperoning signs were displayed in waiting areas; we observed staff ask patients if they wished for a chaperone to be present if they so wished.

Understanding and involvement of patients and those close to them

- Specialist health professionals were available to support patient who had received a diagnosis of cancer or other serious health condition.
- The four patients we spoke with each said they felt they had been well informed of their care journey, and of what to expect when they attended for their scan. We observed health professionals explaining the process and of what to expect when patients entered the MR or CT scanning suite. Radiographers were compassionate and caring and were observed reassuring patients upon their arrival to the department.

Are diagnostic imaging services responsive?

Service delivery to meet the needs of local people

- Spire Southampton Hospital provided a range of diagnostic imaging services ranging from plain x-ray through to computerised tomography (CT) and magnetic resonance imaging (MRI). The service mainly operated from 8am to 10pm Monday to Friday but we saw evidence that the service was able to be flexible with their operating hours and could provide additional services at weekends.
- Staff reported that whilst the MR service ran at full capacity during the week, there was always scope to accommodate urgent requests be it referrals from the inpatient wards or the outpatient department. We observed this on the day of the inspection when an urgent MRI request was received from a consultant in the outpatient department. This meant patients could receive a scan the same day as their outpatient appointment if their clinical condition was such that timely diagnostic assessment was required.
- Individual changing rooms were available to allow for patients attending for MR to change in private. Signs were present on each room to notify staff and others that procedures were underway in those rooms, therefore affording patients a level of privacy.
- Car parking was available within the hospital grounds to accommodate for the high numbers of patients attending for diagnostic imaging or other outpatient activity within the hospital. There was step free access across the hospital allowing for ease of movement for people with reduced mobility or wheelchair users.

Meeting people's individual needs

- Interpreter services were available and staff knew how to contact them should the need arise.
- The MR was dated and was being considered for replacement. As such, it was not possible for the hospital to scan bariatric patients as the machine was not a wide bore MR scanner. This was despite the hospital providing specialist bariatric surgery services. This was recognised as an area for improvement and a business case had been submitted to the Spire Healthcare head office for funding to replace the MR scanner during the 2019/2020 financial year.
- The number of children who attended for diagnostic imaging was relatively small when compared to the overall activity for the department. A small play area was available in the waiting room. On the day of the inspection, we spoke with one parent who had attended with their young child. They reported that staff had acknowledged them and had expedited them through the department in order they remained in the hospital for as little time as was possible. Colourful lead aprons were available for when children attended for plain-x-ray. These could be worn by parents or guardians to reduce their exposure to ionising radiation.
- Hot and cold drinks were freely accessible in the waiting room. Single sex toilets were located throughout the department. Toilets had been equipped with mobility and manual handling assistive equipment to help individuals with reduced mobility to mobilise more easily.
- Ward-based mobile x-ray services were available. These could be provided 24 hours a day with radiographers

supporting an on-call rota. This meant patients who were too sick or those who were restricted to bed, such as those in the critical care unit, could still have x-rays at any time of day or night.

Access and flow

- The MR service operated from 7am to 10pm Monday to Friday; CT operated from 8am to 4pm Monday to Friday. General plain x-ray services operated both a booked appointment system and general walk-in service to allow for patients attending outpatient appointments to also have plain x-rays on the same day.
- The service was able to offer additional scanning sessions on the CT/MR modalities at weekends if demand called for this. The proximity of the hospital to a local NHS trust meant NHS waiting list initiatives could be operated from Spire Southampton Hospital if required to ease pressure on NHS diagnostic imaging services.
- Radiologists worked flexibly to ensure images were reviewed and reported within a timely way. Whilst the diagnostic imaging manager could describe the process they went through to ensure there was no backlog of images, there was no robust auditing process. This was despite an incident in 2018 in which the diagnostic imaging manager identified some 1,300 images dating back to 2013 which had no apparent report logged against them (we have discussed this in detail within the safe domain). The diagnostic imaging manager reported that a daily check of the reporting information system was undertaken and any images not currently allocated for reporting, were assigned to a radiologist to ensure they were reported.
- There was a process for ensuring that any urgent or significant unexpected findings were escalated back to the referring consultant for consideration.

Learning from complaints and concerns

- The diagnostic imaging manager reported the department had received no formal complaints during 2018. However, they could describe the process they would follow in the event a complaint was received.
- A review of the incident reporting system suggested some low level informal complaints had been received from patients. These incidents had been investigated and a response provided to the patient detailing any contributing factors, and any remedial action taken by the service to address the area of complaint. There was evidence the diagnostic imaging manager had afforded an apology to patients as the manager acknowledged that even informal comments warranted an apology, especially if the patient's expectations had not been met.

Are diagnostic imaging services well-led?

Leadership

- The diagnostic imaging service was managed by a diagnostic imaging manager. The post holder had taken up the role in July 2018 but reported they were leaving the organisation two weeks after our inspection. Staff reported there had been no diagnostic imaging manager for a period of 18 months prior to the current post holder starting. Whilst interim arrangements had been made with an existing member of staff acting up in to the role, staff described the absence of a substantive manager as impacting on the operational effectiveness of the service. Some staff told us morale had deteriorated during that time; this was recognised by the hospital director also.
- Staff working in the diagnostic service reported that whilst the current post holder had had some positive impact, they considered the priorities of the manager differed from those of the departments needs and requirements. Further, some staff felt the diagnostic manager was slow to respond to the low morale and had not effectively addressed the concerns of the workforce. Examples were provided of staff feeling bullied or harassed by a senior manager however they had not raised these concerns in order that the service could take appropriate action despite the provider having a Freedom to Speak up Guardian and a whistleblowing process.
- The current post holder reported to the outpatient service manager who in turn reported to the matron who also acted as the clinical services manager. There was no clinical lead or consultant radiologist representation at the Medical Advisory Committee with the post being vacant at the time of the inspection. Some staff spoke anecdotally that radiologists were disengaged and felt generally unsupported, hence the lack of engagement with the hospital management team. This had led to a range of policies and protocols not being approved due to the lack of clinical representation at the medical advisory committee (MAC)

The provider reported that following the inspection, a radiologist had since been approached and accepted the role as a medical advisory committee representative.

Vision and strategy

- Staff could not describe a departmental vision or strategy. The provider subsequently reported that individual specialties were not required to have a local strategy, often due to the size of locations; it was acknowledged that each location had a hospital wide vision and strategy. Staff could describe the vision for the hospital. They also described the wider values of Spire Healthcare. There was limited evidence of staff reviewing and considering how they could deliver and meet the hospital's vision and strategy.

Culture

- The hospital director was candid about the cultural challenges they faced at Spire Southampton Hospital. The hospital was in the midst of a cultural change programme. The hospital director was striving to modernise standards across the hospital. They described some pockets or the workforce who were "Entrenched" in how they worked. The diagnostic imaging department was recognised as one such department, with specific challenges having existed in the x-ray modality. Morale was reported to be low across the department. The diagnostic imaging manager reported an exodus of staff within the x-ray department had led to the recruitment of a new workforce which was considered as a positive outcome for the department. Managers hoped this would help improve standards across the department with staff who had worked in the department for many years, moving to new roles in other hospitals. The introduction of new staff was seen as pivotal. However, there continued to exist a small cohort of staff who described a "Done too" attitude with little in the way of professional accountability or understanding of professional standards. A small number of staff lacked insight in to the implications of not completing quality control or quality assurance processes, despite there being clear regulatory requirements for these to be completed. There was a view among staff that managers were responsible for these areas, and so a lack of progress had been made in gaining traction on areas including quality assurance.

Governance

- The diagnostic imaging manager generated a diagnostic imaging report which was considered at the hospital governance meeting on a quarterly basis. The content of the report was limited and considered department activity, regulatory inspections (if any), staffing levels, risk management and adverse events, safety alerts, safeguarding and staff development. There was no evidence of thematic reviews into incidents having taken place and this was confirmed to be the case with the diagnostic imaging manager. Issues surrounding the lack of grip of quality assurance processes was not highlighted in the report, nor was the lack of discrepancy reporting processes despite this being an area of concern for the department manager. The report did not consider patient experience, department culture, delivery against the hospital's strategy or vision, complaints, or general risk management.
- Governance processes within the diagnostic imaging service were at an embryonic stage. This was supported by the areas we have discussed in the safe and effective domain of this report. Examples included the lack of quality control of ionising radiation equipment, despite concerns being raised by external parties over rate discrepancies of image intensifiers. Staff had not acknowledged the need for robust quality control programmes to exist despite this incident being highlighted in 2018. Staff reported being "Too busy" or "Not competent" as reasons for not completing quality assurance processes despite the significant safety implications of not completing such checks. Staff adopted an almost cavalier attitude towards the requirements of the Ionising Radiation (Medical Exposure) Regulations 2017.
- Whilst a diagnostic imaging scorecard had been developed, the information used to report against the standards set out in the report was inaccurate. Examples included the reporting of visual and physical checks of personal protective equipment (as detailed in the safe domain of this report). In addition, the score card reported that all staff had completed the required competencies in relation to IR(ME)R 2017 requirements; this was found not to be the case with no formal record of any consultant radiologist have been inducted or competency assessed. The hospital director was not aware of this, nor were they aware of the lack of discrepancy reporting processes in the department. This

further supported the notion that the diagnostic imaging report required further attention to ensure it provided sufficient assurances over the safety of the diagnostic imaging service.

Managing risks, issues and performance

- The department managed a locally held risk register which contained two risks relating to equipment and the environment. There was no reference to the poor compliance with quality assurance checks or quality control protocols. Further, the lack of engagement of the consultant radiologist body, or lack of discrepancy reporting process were not escalated as risks despite these being considered as some of the more significant risks faced by the department. This therefore raised concerns over the management of risk within the department, and the ability of the hospital management team to have effective oversight of the service.

Managing information

- The department used a range of computer systems to manage the diagnostic imaging service. Staff told us the reporting information system (RIS) was antiquated though the provider confirmed that this is a nationally recognised imaging system in use by several providers, both independent and NHS, and was considered by the provider to be fit for purpose.
- General housekeeping of information technology systems was poorly audited with staff only being able to provide verbal assurances that systems were checked weekly to ensure no images remained unreported.

Engagement

- Due to the unannounced nature of this inspection, we did not explore this key line of enquiry.

Learning, continuous improvement and innovation

- Due to the unannounced nature of this inspection, we did not explore this key line of enquiry.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

The provider must operate a robust quality assurance and quality control process (Regulation 17(1)(2)(a)(b)

The provider must operate an effective governance process (Regulation 17(1)(2)(a)(b)

The provider must ensure that action is taken to ensure the safety of staff and visitors is maintained in accordance with the Ionising Radiation (Medical Exposure) regulations 2017.

Action the provider SHOULD take to improve

The provider should review their safeguarding policy to ensure it is up to date and reflects current best practice.

The provider should review the equipment located near to the MR scanner to ensure it is appropriate and compatible for use in emergency situations.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance **The provider must operate a robust quality assurance and quality control process (Regulation 17(1)(2)(a)(b)** **The provider must operate an effective governance process (Regulation 17(1)(2)(a)(b)**