# IR(ME)R annual report 2019/20

CQC's enforcement of the Ionising Radiation (Medical Exposure) Regulations 2017

October 2020

## The Care Quality Commission

The Care Quality Commission is the independent regulator of health and adult social care in England.

We make sure that health and social care services provide people with safe, effective, compassionate, high-quality care and we encourage care services to improve.

### Our role

- We register health and adult social care providers.
- We monitor and inspect services to see whether they are safe, effective, caring, responsive and well-led, and we publish what we find, including quality ratings.
- We use our legal powers to take action where we identify poor care.
- We speak independently, publishing regional and national views of the major quality issues in health and social care, and encouraging improvement by highlighting good practice.

We are also the enforcement authority for the Ionising Radiation (Medical Exposure) Regulations, known as IR(ME)R, in England.

### Our values

- Excellence – being a high performing organisation.
- Caring – treating everyone with dignity and respect.
- Integrity – doing the right thing.
- Teamwork – learning from each other to be the best we can.

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# SUMMARY

CQC enforces the Ionising Radiation (Medical Exposure) Regulations, known as IR(ME)R, in England. The regulations aim to protect people against the dangers from exposure to ionising radiation in healthcare settings. We receive and investigate notifications of radiation incidents where patients have received an accidental or unintended exposure, and we inspect IR(ME)R employers to ensure they comply with the regulations.

## Key findings in 2019/20

Because of the coronavirus (COVID-19) pandemic, we paused our routine IR(ME)R inspections in March. Our temporary response, along with the other UK inspectorates, resulted in a slight change to regulatory requirements and clinical practices. The challenges from COVID-19 meant that staff needed to quickly adapt to many changes, which requires strong leadership and support to manage in stressful and demanding times. We found that the workforce responded in innovative ways, which we encourage.

A number of employers contacted us during the COVID-19 pandemic as they were risk-assessing potential shortages in their workforce due to staff sickness or re-deployment and we were asked to consider allowing physician assistants or associates to act as referrers for medical exposures. Although we cannot change legislation, we suggested that other staff who are registered professionals could help to reduce the pressure, as radiologists, nurses and radiographers can all be entitled to act as an IR(ME)R referrer, and any non-medical referrer can be trained and audited to follow local arrangements.

In our work, we often encountered confusion around justification and authorisation of medical exposures. We emphasise that employers need to carefully consider the role of the practitioner and the associated training required for radiographers as operators.

A further concern from our work related to shortages of medical physics experts. We believe there is not enough emphasis on the importance of the medical physics expert and the physics workforce generally. Under the regulations, the expected level of involvement from medical physics experts has increased, but this has not been matched with additional resources. Scientific staff need appropriate resources and time to quality assure equipment and fulfil all the duties under the regulations but have had to take on more work with no increase in the workforce.

## Statutory notifications of errors: 3 June 2019 to 31 March 2020

Under IR(ME)R 2017, the definition for making statutory notifications of incidents changed to 'significant accidental and unintended exposures' (SAUE). This came into effect on 3 June 2019, therefore the reporting period for SAUE notifications in this report is based only on notifications received from 3 June 2019 to 31 March 2020.

We do not include notifications received between 1 April and 2 June 2019 as they were reported under the previous much greater than intended (MGTI) thresholds. The data therefore relates only to a 10-month period in 2019/20, so we compare data with a calculated 10-month equivalent period in 2018/19. We also received fewer SAUE notifications from March 2020 as a result of the coronavirus (COVID-19) pandemic.

In 2019/20, 44.5 million diagnostic imaging examinations were carried out on NHS patients in England, of which 30.5 million used ionising radiation.[a] Activity across all types of imaging dropped slightly from 44.8 million the previous year, potentially due to the impact of COVID-19 on imaging numbers in March 2020.

We received 407 notifications during this 10-month period, which represents a significant reduction of 52% from the same period last year (841). This is to be expected following the change in reporting thresholds introduced with the new SAUE guidance in June 2019, where we aimed to reduce the number of very low risk notifications that need to be reported.

### Diagnostic imaging:

- 247 notifications – a reduction of 63% from the same period last year; these comprised 61% of all notifications received, down from 79% in 2018/19
- the diagnostic sub-modality with the highest proportion of notifications was computed tomography (CT)
- the most common type of error is still when the wrong patient receives an exposure, with 28% of all diagnostic imaging errors resulting from referrers failing to refer the right patient

### Nuclear medicine:

- 47 notifications – a reduction of 25% from the same period last year; these comprised 12% of all notifications received
- most notifications were from diagnostic nuclear medicine (91%)
- the majority of notifications (60%) involved errors relating to incorrect referrals and equipment failure

### Radiotherapy:

- 113 notifications – a reduction of 2% from the previous year; these comprised 28% of all notifications received
- nearly half of all notifications (49%) related to planning and verification imaging
- the most common errors involved selecting verification protocols and shift errors.

## Inspections

In 2019/20, we carried out 35 inspections (25 inspections in 2018/19). These included 29 under IR(ME)R, which were either proactive inspections as part of a programme or reactive inspections in response to concerns or high-risk notifications. We also joined six inspections with colleagues under the Health and Social Care Act.

[a] Examinations including plain film X-rays, CT, fluoroscopy, nuclear medicine, PET-CT and SPECT. See appendix for definitions.

### Enforcement action

Poor compliance with the regulations is often the result of an inadequate governance framework around radiation protection. We issued Improvement Notices under IR(ME)R to nine IR(ME)R employers following both proactive and reactive inspections.

Most enforcement action was under Regulation 6 in response to failures relating to procedures and protocols, where these were either missing, out of date or did not reflect clinical practice. In several cases there was insufficient support from medical physics experts for the service.

## Actions for IR(ME)R employers

We continue to see high numbers of errors resulting from inadequate checks. All IR(ME)R duty-holders must be vigilant and follow procedures and safe practices such as multi-point checks at all stages in the patient's pathway. Based on our findings, we recommend some actions for IR(ME)R employers to improve both compliance with the regulations, as well as the safety and quality of patient care. We summarise these below and provide more detailed recommendations in the sections for each modality.

### 1. Documentation

- Differentiate the 'policy' aspects from the 'clinical instructions' of IR(ME)R documentation. It may be useful to separate these so that the working procedures only include the relevant information for the intended audiences, with separate high-level 'managerial' procedures.

### 2. Equipment

- Continually monitor and manage risk where equipment falls below normal standards of performance. This may be through a risk register. Consider how the equipment is used and limit its range where appropriate. Address faults with the equipment manufacturer first, but also report persistent issues to the Medicines and Healthcare products Regulatory Agency (MHRA).
- Make sure medical physics experts continue to get support from, and share experiences with, special interest groups and the Institute of Physics and Engineering in Medicine, particularly where issues may be widespread.
- Systems with a history of unreliability, and equipment still in clinical use – both towards and past its end of life – should have more scrutiny in terms of both quality control and routine maintenance. Medical physics experts should review the frequency and effectiveness of routine checks in these systems.
- Involve medical physics experts in decisions on purchasing any new piece of equipment to ensure the correct technical specification, and when making any changes to equipment that will affect image quality and patient dose. Include and consult them in any optimisation programme.

## 3. Workforce

- Carefully consider the requirements for the medical physics workforce, taking into account the increased regulatory requirements. Include the number of medical physics staff in procurement business cases for new equipment, ensuring there is appropriate resource to quality assure equipment and fulfil all duties under Regulation 14.

## 4. Transgender patients

- Make sure that procedures in imaging and radiotherapy departments are inclusive of transgender and non-binary patients, including the procedure for making pregnancy enquiries.

## 5. Licensing in nuclear medicine

- Maintain a process for managing licences and certificates to administer radioactive substances. This includes reviewing those of practitioners transferring from other sites, and when entitling new practitioners.
- Where there are gaps in licensing arrangements, notify CQC using the licensing webform, to demonstrate good governance and to support thematic analysis.

## 6. Justification and authorisation

- Carefully consider the role of the practitioner and the associated training needed for radiographers who may be entitled within local procedures to act in this capacity.
- Entitling practitioners to justify and authorise treatments at other centres, such as in cancer alliances, will enable trusts to widen the scope of treatment they offer. However, any entitlement process must be robust and clearly documented within the employer's procedures.

# INTRODUCTION

November 2020 is the 125-year anniversary of the discovery of X-rays. Over this time, ionising radiation has been fundamental to the diagnosis, surveillance and treatment of a variety of conditions, from dental check-ups, chest X-rays, CT scans, and cancer treatments using external beam and internal radiotherapy.

The Ionising Radiation (Medical Exposure) Regulations, known as IR(ME)R, provide a regulatory framework to protect people against the dangers from exposure to ionising radiation. The regulations state that exposures need to be individually justified and optimised to ensure that the benefit outweighs the risk.

CQC enforces the regulations in England, and in this report, we provide an update on the findings from our inspections and notifications that we receive of 'significant accidental or unintended exposures' (SAUE). We share an overview of compliance with the regulations, and examples of the actions that IR(ME)R employers have taken to improve the quality of care, so that other employers, healthcare professionals and academic bodies can learn from them.

We published new guidance on what constitutes a notifiable incident under IR(ME)R17 in June 2019, which was updated in August 2020. As with any new guidance, there have been some inconsistences with the interpretation and a need for further clarification, which we discuss in this report.

Since 2018, we report on notifications received in the year 1 April to 31 March. However, we can't compare the numbers of notifications received in this reporting period with those published in previous reports. This is because:

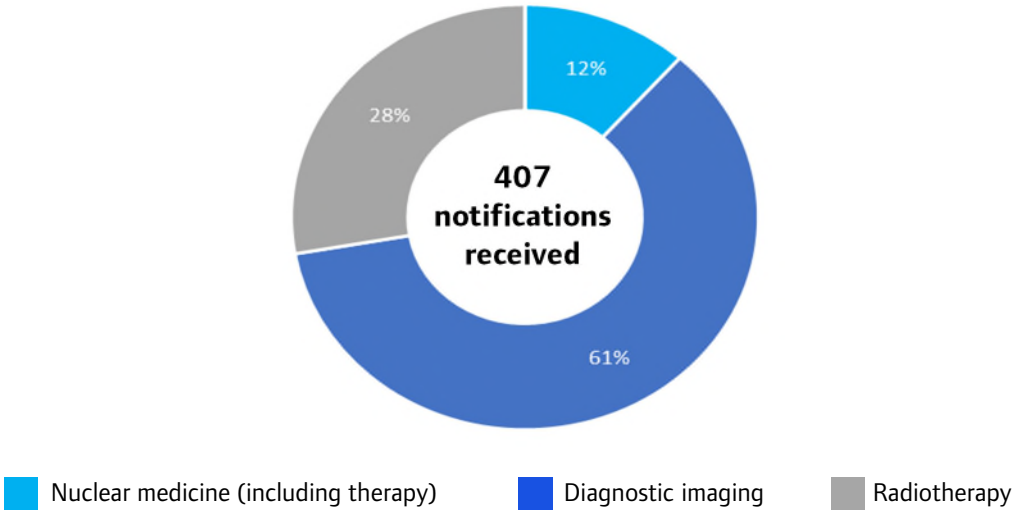
- SAUE guidance and reporting thresholds came into place on 3 June 2019. As a result, we have only analysed notifications received between this date and 31 March 2020. Future reports will consider data from each financial year
- activity in quarter 4 of 2019/20 was affected by the COVID-19 pandemic, therefore there were fewer notifications as many treatments and investigations were paused
- some notifications may also have been re-classified to a different category following further investigation of previously open notifications.

# OVERVIEW OF ACTIVITY IN 2019/20

## Notifications

During the period 3 June 2019 to 31 March 2020, we received 407 notifications across all modalities (figure 1). This was a major reduction of 52% compared with 2018/19 where we received 841 over a similar period. This was expected following the change in reporting thresholds introduced with the new SAUE guidance in June 2019, where we aimed to reduce the number of very low risk notifications that need to be reported.

**Figure 1: Notifications received by modality, 3 June 2019 to 31 March 2020**




### Activity data in England

NHS England's Diagnostic Imaging Dataset collects information about tests carried out on NHS patients in England. The data for 2019/20 showed that 44.5 million diagnostic imaging examinations were carried out, of which 30.5 million[1] used ionising radiation.[b] Activity across all imaging modalities dropped slightly from 44.8 million the previous year.[2] However, because of the impact of the COVID-19 pandemic, only 2.73 million imaging tests were carried out during March 2020, compared with 3.85 million during March 2019 (a decrease of just over 29%).

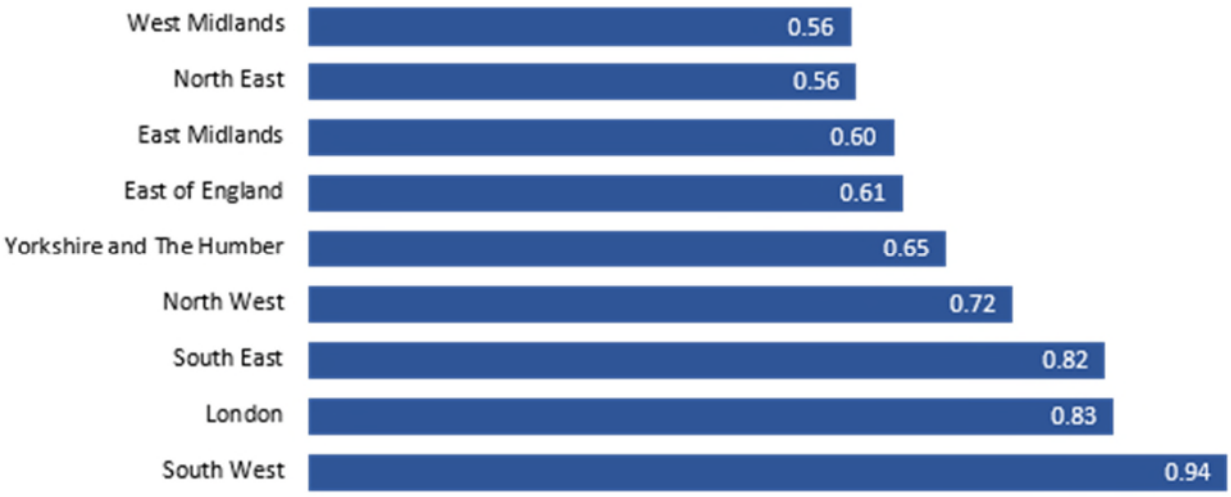
The National Cancer Registration and Analysis Service (NCRAS) produces data for the Radiotherapy Dataset (RTDS), which monitors all radiotherapy activity delivered in NHS hospitals in England.[3] In 2018/19, there were nearly 136,000 episodes of radiotherapy treatment in England, an increase of around 2% over the previous year.

[b] Examinations including plain film X-rays, CT, fluoroscopy, nuclear medicine, PET-CT and SPECT.

### Geographical distribution of notifications

We have analysed the number of notifications received in each region as a rate per 100,000 people. This shows a variation from 0.56 notifications in the West Midlands to 0.94 in the South West (figure 2). We cannot be sure of the cause for the variation, although it could include differing interpretations of the SAUE guidance.

**Figure 2: Number of notifications per 100,000 population, 3 June 2019 to 31 March 2020**




## Inspections

In 2019/20, the IR(ME)R team carried out 35 inspections (figure 3). This includes six inspections carried out under the Health and Social Care Act with inspectors from our Hospitals Directorate. The remaining 29 inspections under IR(ME)R were:

- **12 proactive inspections** as part of a programme of inspections, such as interventional radiology, or other proactive inspections based on intelligence. In some cases, we carried out two-day inspections across two departments at the same IR(ME)R employer, for example in diagnostic imaging and radiotherapy. These are counted as two separate inspections.
- **8 reactive inspections** in response to a notification or information of concern.
- **2 joint inspections** carried out alongside another regulator such as the Health and Safety Executive (HSE).
- **7 follow up inspections** where we have revisited to check compliance with previous enforcement action or to ensure that an IR(ME)R employer has made improvements.

**Figure 3: Number of inspections per quarter, April 2016 to March 2020**

| | 2016/17 | 2017/18 | 2018/19 | 2019/20 |
|---|---|---|---|---|
| Q1 | 5 | 5 | 4 | 10 |
| Q2 | 4 | 5 | 8 | 9 |
| Q3 | 1 | 5 | 7 | 8 |
| Q4 | 5 | 2 | 6 | 8* |
| **Total** | **15** | **17** | **25** | **35** |

* Inspection activity paused in March 2020 because of COVID-19 pandemic

Following these inspections, we made 52 recommendations for IR(ME)R employers to improve compliance and care for patients. These included some common themes:"

- Seven employers had failed to ensure they had a full equipment inventory as required under Regulation 15(2). There was a common lack of the dates of installation/manufacture. In radiotherapy, treatment planning and oncology management systems were often missing from inventories.
- We saw problems with written procedures or protocols in 12 employers. This included references to outdated regulations, lack of ratification and other aspects associated with controlled documents, as well as insufficient information to support clinical staff in their roles under IR(ME)R. Some nuclear medicine departments failed to include information about the need to provide written information and instructions for patients.
- We made six recommendations in relation to testing equipment. This included addressing backlogs of quality control testing of equipment, a lack of information about remedial action taken following test failures, and a review of quality control frequency for ageing equipment.
- In three cases, guidelines on referring patients were not available to all referrers, such as GPs, and in some cases, guidelines did not include areas such as interventional radiology or cardiology.

Appendix B provides a full list of our recommendations to share the learning from these inspection reports.

## Enforcement activity

In 2019/20, we served nine improvement notices under the Health and Safety at Work etc. Act 1974. Two were in nuclear medicine departments and seven in diagnostic imaging and interventional radiology departments. The notices referenced 34 breaches under IR(ME)R:

- 17 breaches (in eight employers) related to Schedule 2 employer's procedures and protocols including:
    - missing or out-of-date procedures (Regulation 6(1)) or protocols (Regulation 6(4))
    - not reflecting clinical practice and therefore not useful or being used by clinical staff (Regulation 6(2))
    - failure to maintain a QA programme for procedures and protocols (Regulation 6(5)(b)).
- 3 breaches (in three employers) related to justification and authorisation of exposures (Regulation 11(1)b), and 11(5)) including:
    - no arrangements for justification of surgical procedures (such as orthopaedic theatres)
    - failure to entitle staff appropriately to act as practitioners
    - failure to provide suitable authorisation guidelines to operators
    - guidelines that were not signed off by the responsible practitioner.
- 5 breaches (in three employers) directly related to the input of medical physics experts. In most cases this related to inadequate support by an external medical physics service, although we also saw that in-house departments were understaffed in relation to the equipment and services that they supported. We often saw evidence of this in a backlog of routine equipment testing and inadequate optimisation programmes.

Other breaches included:

- Regulation 17(4) – two employers did not have up-to-date training records available for inspection. These records must include the dates and nature of the training provided for all practitioners and operators – not just recent recruits.
- Regulation 6(5)(a) – one employer did not have referral guidelines.
- Regulation 8(2) – one employer did not conduct a thorough study of the risk of accidental or unintended exposures for a nuclear medicine therapy service.

Our website provides further details on the enforcement notices we have issued.

# Key findings from inspections and notifications

The following key themes identified in 2019/20 were common to all modalities. We hope that IR(ME)R employers can learn from them and improve their own compliance.

## Incident management

### Timeframes for making notifications

IR(ME)R Regulation 8(4)(b)(ii) sets out the requirement to make a notification. To enable employers to conduct preliminary investigations and obtain a dose assessment, the SAUE guidance specifies a maximum of two weeks after detecting the incident.

In this reporting period, we looked at the number of days between the date of the incident and date of notification. Although we were unable to immediately identify outliers (for example because of a delay in identifying the incident or incorrect dates on the notifications) the average number of days was 20 (median) with a range of zero to 1,388 days. This was a slight decrease compared with the 21 days last year, which may suggest that the reporting timescale introduced with the SAUE guidance is having an impact.

**SAUE code M (multiple patients)**

We have seen inconsistency in how employers have interpreted the definition of 'multiple patients' and how they relate to the notification thresholds. The SAUE guidance defines multiple patients as more than one person involved in a particular incident or theme. These are notifiable regardless of dose and the thresholds given in the reporting codes 1 to 9.2.

This category is designed to check compliance with Regulation 8(3), ensuring that employers have processes in place to identify and track themes in incidents. It also helps us to identify areas of risk that are not picked up under the other SAUE definitions.

## Example of notification involving multiple patients

**Background:** 15 patients were involved in similar type of incident over a five-month period. These involved incorrect detector selections in a DR plain film X-ray room.

Each patient received a dose that was under the notification threshold, but after a theme was identified during a routine review of all incidents, these were notifiable under the 'multiple' code.

**Investigation:** The 15 incidents were grouped in several categories based on their root causes, which were:

- ineffective communication between operators
- fatigue, where three of the incidents happened during night shifts
- working automatically without 'pausing and checking' as well as checking the detector selection
- a patient who was difficult to position, which led to rushing examinations or changing techniques at the last minute
- distractions from patients or other members of staff, which meant radiographers were distracted from usual embedded routines
- the design and age of equipment, as the unit did not have some of the more modern safety features that would have prevented an exposure if the tube was not directed at a detector; along with other factors, this meant the system was not user-friendly.

**Actions taken:**

- **Working with the manufacturer.** The radiology department met with the manufacturers to discuss the incidents in detail. Together, they identified a list of actions and potential equipment modifications that could help reduce the risk of these incidents happening again. These included changing the warning message displayed and amending the auto-positioning defaults on the system.
- **Training.** After the wording of the warning message was changed, the manufacturer also provided updated applications training on the system for all staff.
- **Reviewing pause and check.** The department felt that the existing Pause and Check list was too long or too difficult to go through for each exposure. This was reviewed and split into three phases to help match more closely the working patterns of the staff. There was also a review to identify how pause and check could be better embedded, such as more prominence in staff training and induction for staff.
- **Reviewing staff processes.** The department clarified processes to ensure consistent practice, such as identifying a lead operator when several staff are working together, and ensuring that detectors are stored consistently when not being used.

# Key issues in 2019/20

## Effects of the coronavirus (COVID-19) pandemic

We paused our routine inspections under IR(ME)R in March and implemented a temporary response, along with the other UK inspectorates, which highlighted:

- the need for training and supervision when staff were redeployed, and to ensure that no staff operate radiological equipment without training
- the entitlement of final year students and former registrants as duty-holders
- the need to prioritise testing of essential and high-dose equipment
- changes to administering radioactive substances where services needed to relocate to alternative sites, including the regulatory requirements and IR(ME)R employer's licence.

### Nightingale hospitals

During the acute phase of the COVID-19 outbreak, the government announced that Nightingale field hospitals would be set up across the country. NHS Nightingale hospitals presented a unique situation, as IR(ME)R employers had to consider slightly different approaches to regulatory requirements and clinical practices. The following example shows an employer's responses.

#### Example - Nightingale emergency preparedness

One of the first Nightingale hospitals produced a close working relationship between the site radiation protection leads and the relevant regulators (CQC and the Health and Safety Executive), which helped in developing a set of documents, including IR(ME)R employer's procedures. As well as complying with the regulatory requirement, these also provided clear and useful clinical support to radiographers and other clinical staff working in the hospital.

The initial documentation was based on a large capacity intensive care unit with space for up to 2,000 ventilated patients at any one time. It therefore concentrated on a very specific scope of practice, with supporting documentation held at a wider trust level. The basic work instructions were designed solely for the staff carrying out the X-rays and included very targeted work instructions for:

- how to identify the patient
- what information is needed and where to record it on the radiology information system (RIS), for example who is acting as the practitioner, the dose information, and the comments required
- who can request and justify examinations
- how and when to report a radiation incident.

Where procedures were not directly relevant for the frontline staff and their specific scope, details were listed in a 'level 1' policy type document, which explained why they were not relevant, i.e. based on a risk assessment. Examples included carers and comforters, who were not allowed in the clinical areas as for hospital policy, or research exposures. These were covered under the trust-wide policies.

There was also a 'level 2' set of procedures aimed at the lead radiographers or governance leads. These documents included how to investigate radiation incidents, what to do when diagnostic reference levels (DRLs) are consistently exceeded or any other information specifically relevant to their intended audience.

In last year's annual report, we recommended that procedures should be designed to be more locally relevant and this is a good example of where this has been implemented well.

For many years in diagnostic imaging services, we have almost exclusively found sets of employers' procedures with a great deal of policy level content, which were directed at such a huge range of audiences that they provided little practical information.

## Recommendation

**Employers need to consider differentiating the 'policy' aspects to the 'clinical instructions' of IR(ME)R documentation. It may be useful to separate these so that the working procedures only include the relevant information for the intended audiences, with separate high-level 'managerial' procedures.**

## Procuring equipment

The COVID-19 pandemic also resulted in changes relating to centralised purchasing of new equipment, with little input from employers. A number of mobile X-ray machines were fast-tracked into the market, although many employers told us this led to difficulties in procurement and initial assessment.

The medical physics community stepped up to the challenge and worked hard to evaluate the equipment and share findings both with the suppliers and members of the Institute of Physics and Engineering in Medicine (IPEM). We are grateful to the early adopters of this equipment and IPEM for their collaborative work.

## Recommendation

**Where equipment falls below normal standards of performance, it is important to continually monitor and manage the risk. This may be through a risk register. Active feedback to the supplier would also enable them to track any trends or find fixes in the future. Employers should consider how the equipment is used and limit its range where appropriate. For example, where the quality of images is poor, employers should consider not using the machines for neonatal chest X-rays.**



**Medical physics experts should continue to get support from, and share experiences with, special interest groups and the Institute of Physics and Engineering in Medicine – particularly where issues may be widespread.**

## Physician associates

A number of employers contacted us during the COVID-19 pandemic as they were attempting to risk-assess a potential reduction in their workforce due to staff sickness or re-deployment. As an enforcement authority, we were asked to consider allowing physician assistants or associates to act as referrers for medical exposures.

While we fully appreciated the pressing and growing clinical situation across all employers, it was not within our powers to relax legislation, as this is always a matter for the Department of Health and Social Care. Physician assistants are not registered healthcare professionals under the Health Care Professions Act 2002, therefore allowing them to act as referrers would be a direct breach of the IR(ME)R statutory instrument. We suggested an alternative approach during this period of considering whether other staff in organisations who are registered professionals could help to reduce the burden. For example, radiologists, nurses, and radiographers can all be entitled to act as an IR(ME)R referrer, and any non-medical referrer can be trained and audited to follow local arrangements.

## Stress in the workforce and staffing issues

The challenges from COVID-19 meant that staff needed to quickly adapt to many changes, and resulted in issues including:

- changes to processes, protocols, normal established practices (for example, infection prevention and control, scans, and new equipment)
- staff shielding themselves because they or their families were in vulnerable groups, or issues with childcare, which meant the remaining workforce had to cover the additional gaps
- staff feeling stressed as they were often working in potentially unsafe conditions influenced by excessive tiredness, anxieties about the pandemic itself, and a lack of personal protective equipment (PPE) in the early stages of the pandemic
- some staff groups reporting long-term periods of sickness due to stress at work, and feeling that the NHS was being run on goodwill at times as they carried on working excessive hours to ensure patient care was not affected, feeling pressured to work additional hours, and often working through their rest periods.

It will take a long time to return to a normal workflow and there is a continued need for innovation and strong leadership.

### Recommendation

**IR(ME)R employers should support staff who wish to have counselling, and debriefing sessions should be offered to staff groups. Despite pressures, employers should encourage staff to take their breaks and annual leave to allow for adequate rest periods between shifts. Staff returning from periods of stress-related sickness should be adequately supported and offered a phased return to work.**

**Vacant posts should not be frozen where possible, and recruitment drives should continue.**

**Strategic planning is vital to prepare responses for any future outbreak. Employers need to carry on using the new ways of working where possible and further innovate.**

## Pregnancy enquiries in transgender patients

IR(ME)R employers must use inclusive language in their policies and procedures. This must also include procedures for establishing whether a person is or may be pregnant or breastfeeding, as required under the IR(ME)R regulations.

### Example – pregnancy in a transgender patient

We received a notification where a patient was referred for an inpatient CT scan of their abdominal region. The patient was titled 'Mr' on the radiology information system (RIS), had a gender-neutral forename and a male appearance, and declared themselves as male on attendance at the emergency department. The patient's sex was recorded on the RIS as female, but this was not noted at the time. Due to the patient's appearance, name and title, the operator had no reason to refer to the department's pregnancy procedure, which required them to ask only female patients if they could be pregnant.

When the scan was reported, it was discovered that the patient was pregnant. The referrer was contacted, and it transpired that the patient was transitioning from female to male, but the clinical team were not aware of this. As a result, this could not have been communicated to radiology as part of the CT request.

In some cases, it is a criminal offence to disclose a patient's previous gender without their consent, and in all cases patients must be able to expect that their privacy is not violated. In health care, this information may be disclosed on a need to know basis, where it is not possible to gain the patient's consent. It is therefore not always possible for referrers to identify that a patient is transgender when making an imaging request.

In this instance, the employer addressed the incident by developing posters for their imaging waiting areas, alongside their equality and diversity team and various LGBTQ+ groups and advisory bodies. The poster highlights the need to disclose a possible pregnancy to a member of staff. It also contains the following text alongside an NHS rainbow symbol:

*"We are committed to ensuring patients are free from discrimination regardless of their gender or sexual orientation.*

*If your gender was female at birth and you are transgender or non-binary, please inform a member of staff as we legally need to rule out the possibility of pregnancy before we can go ahead with some of our examinations. This information will not be recorded or shared without your consent."*

The employer also developed a high-level transgender policy and shared the risks associated with non-disclosure of trans status with clinical teams, as well as local LGBTQ+ services.

### Recommendation

**Imaging and radiotherapy departments should ensure that their procedures are inclusive of transgender and non-binary patients, including the procedure for making pregnancy enquiries. To respect the patient's privacy, they should be encouraged to disclose their gender history and status, without fear of it being recorded or shared without their consent. This may be achieved using posters with inclusive and accessible language around gender. Staff working in imaging and radiotherapy departments should also be trained in how to approach these matters through conversation while respecting the dignity and privacy of patients.**



## Shortages of medical physics experts

Over the last 18 months, we have served several enforcement notices that were the result of a shortfall in the medical physics workforce. Regulation 14 sets out the need for the employer to appoint a medical physics expert (MPE) and describes the requirements for involving them. Under IR(ME)R 17, the level of involvement of MPEs has increased to include providing advice on radiation protection and regulatory compliance, procurement and technical specifications of equipment, as well as training of practitioners and other relevant staff. However, IR(ME)R does not specify staffing numbers and employers have at times not been able to fulfil the requirements of Regulation 14 because of chronic vacancies in the medical physics workforce.

We believe that there is not enough emphasis on the importance of the MPE and the physics workforce generally. Their better-defined responsibilities under the regulations have not been matched with more resources, meaning scientists are required to undertake more work with no increase in the workforce.

Inspectors have raised concerns around the lack of MPE involvement in optimising equipment and a lack of resources to adequately support dose audits and adopting local diagnostic reference levels. Equipment is often purchased with limited or no involvement of the MPE and

quality assurance of equipment is at times not carried out in a timely way because of staff shortages.

The regulations have increased the expectation of MPE involvement, which places the onus on employers and the medical physics community with little consideration of how to achieve this in practical terms within the current economic constraints.

NHS trusts have not used image optimisation teams (IOTs) as widely as expected following the COMARE16 report[4] and IR(ME)R 17. Trusts also appear to expect that the IOT should be an MPE-led initiative. We feel that they should be led by a clinician and adopt a multi-disciplinary team approach with effective clinical leadership.

### Recommendation

**IR(ME)R employers must carefully consider the requirements for the medical physics workforce, taking into account their better-defined responsibilities under the regulations. The number of medical physics staff should be included in procurement business cases for new equipment, and scientific staff should have appropriate resources and time to quality assure equipment as well as fulfil all the duties under Regulation 14.**

**MPEs should be involved in decisions on purchasing any new piece of equipment to ensure the correct technical specification, and when making any changes to equipment that will affect image quality and patient dose. MPEs should be integral members of any optimisation programme and consulted appropriately.**

## Justification and authorisation

We often encounter confusion around justification and authorisation of medical exposures. Regulation 11 relates to justification of individual exposures and Regulation 10 lays out the duties of the practitioner whose role is to justify and authorise. With advanced radiographic practice continuing to expand we see an increasing number of radiographers cited in employer's procedures as being assigned the task of justification. This is across all modalities but is especially noted in CT and plain film X-ray.

Justification is an intellectual activity and is the primary role of the practitioner. It requires a number of considerations to be taken into account for each individual exposure, including the dose delivered to the individual and the net benefit arising from the exposure. Authorisation is the written confirmation that justification has taken place and again is the role of the practitioner. Sometimes it is not practical for a practitioner to do this, and authorisation is delegated to the operator, predominantly in plain film and CT, often following NICE guidelines. This delegation is most commonly written down as authorisation guidelines, which are ratified by the practitioner who retains the responsibility for the justification of the exposure. **An operator authorising under such guidelines is not a practitioner and is not carrying out justification.**

Radiographers and other healthcare professionals can be entitled as IR(ME)R practitioners and many departments are allowing advanced practice in this field. However, practitioners must be registered healthcare professionals and must have associated training and entitlement to act in this capacity and must work within a defined scope of entitlement.

It is a common misconception that undergraduate training for radiographers incorporates the requirements of practitioner training. But the role of the practitioner requires either advanced post graduate practice or additional training. The enforcement authority does not encourage newly-qualified radiographers to be entitled as practitioners.

Another misunderstanding is between an IR(ME)R practitioner and an assistant or advanced practitioner in other branches of radiography and healthcare. The IR(ME)R practitioner is a specific duty holder within the regulations whose sole role is the justification of medical exposures.

### Recommendation

**IR(ME)R employers must carefully consider the role of the practitioner and the associated training required for radiographers who may be entitled within local procedures to act in this capacity. It is important to consider Schedule 3 of IR(ME)R and adequate training to carry out the task, as well as guidance from the Society of Radiographers[5] and the Royal College of Radiologists. It is also important to differentiate between the IR(ME)R practitioner and other practitioner roles in healthcare.**

## Cancer alliances

Cancer alliances have been created across England to bring together clinical and managerial leaders from different trusts to enable more effectively planned care across local cancer pathways. They have several priorities, including increasing capacity, encouraging cross-organisation working, and brokering agreements between employers to balance supply and demand more effectively across the system.

This presents some challenges, as not all cancer centres have the necessary expertise or experience to plan and deliver some complex treatments. Currently this means that some sites are limited in what they can provide, and patients need to travel for treatment. Although collaborative working will mean an increased level of care for patients, it presents issues relating to sharing expertise across centres.

### Example of a cancer alliance in radiotherapy

Trust A and trust B are in a cancer network. Trust A is routinely offering SABR for oligometastatic cancers but is limited with how many patients it can treat at one time because of machine availability. Trust B does not have any practitioners with experience in planning and treating these patients, but it does have the capacity. Within trust B's employer's procedures, it can entitle a practitioner from trust A to plan and prescribe within the trust, as long as they can satisfy themselves of their abilities and document this process appropriately.

## Recommendation

**Entitling practitioners to justify and authorise treatments at other centres will enable trusts to improve the breadth of treatment they offer. However, it is vital that any entitlement process is robust and clearly documented within the employer's procedures for it to comply with IR(ME)R regulations.**

# DIAGNOSTIC IMAGING

## Notifications in 2019/20

**We received 247 diagnostic imaging notifications between 3 June 2019 and 31 March 2020. This was a 63% decrease compared with the same period last year. Diagnostic imaging comprised 61% of all notifications received during this reporting period. Of all diagnostic imaging notifications, 93% were from NHS acute trusts.**

The diagnostic imaging sub-modality with the highest proportion of notifications was computed tomography (CT) (figure 4), which is the same as the previous year. However, the proportion of CT notifications across all diagnostic imaging sub-modalities increased from 47% to 68%. This is due to the substantial decrease in the number of notifications received in the plain film X-ray modality (301 in the same period last year and 45 in this reporting period).

**Figure 4: Notifications received by sub-modality, 3 June 2019 to 31 March 2020**

| Sub-modality | Number of notifications | % notifications |
|---|---|---|
| CT | 169 | 68% |
| Plain film X-ray | 45 | 18% |
| Interventional radiology/cardiology | 17 | 7% |
| Dental (including CBCT) | 7 | 3% |
| Mammography | 6 | 2% |
| General fluoroscopy | 2 | 1% |
| DXA | 1 | <0.5% |
| **Total** | **247** | **100%** |

### New internal category codes

In June 2019, the Clinical Imaging Board (CIB) released a coding taxonomy, similar to the 'Towards Safer Radiotherapy' taxonomy concept first released in 2009.[6, 7] This covers all incidents, including near misses and non-notifiable incidents.

The error coding taxonomy aims to:

- identify potential patterns of errors and near misses
- facilitate interdepartmental comparison and sharing of good practice
- identify areas where patient safety could be improved on a national scale.

Although the use of this taxonomy is not mandatory, we have seen the benefits, as using this system and its associated reviews can be used as evidence for Regulation 8(3).

Along with the new SAUE guidance published in June 2019, we reviewed our internal error coding, and revised it to more closely align with the CIB codes. For example, using the tiering system:

- Tier 1 - which duty holder the error originated from
- Tier 2 - the point in the pathway that the error first occurred
- Tier 3 - what went wrong.

Some codes have been expanded or have been combined to ensure they fit the types of notifications we receive. With the updated SAUE guidance published in 2020, the new webform also gives the opportunity for reporters to provide any CIB codes.

## Types of error

We have not directly compared with last year's data because of the significant change in number, criteria change, and our internal criteria changes as previously discussed. Figure 5 shows the errors based on our new internal taxonomy.

**Figure 5: Notifications received from diagnostic imaging by detailed error type, 3 June 2019 to 31 March 2020**

| Tier 1 | | Tier 2 | | Tier 3 | |
|---|---|---|---|---|---|
| Employer | 1 | Procedure | 1 | Inadequate procedures | 1 |
| Referrer | 103 | Incorrect referral | 74 | Wrong patient | 68 |
| | | | | Wrong modality | 3 |
| | | | | Wrong anatomy | 1 |
| | | | | Wrong timing | 2 |
| | | Referral information | 29 | Failure to cancel a request | 12 |
| | | | | Insufficient/inaccurate | 12 |
| | | | | Duplicate/no check of previous | 4 |
| | | | | Illegible handwriting | 1 |
| Practitioner | 2 | Patient safety checks | 1 | ID error | 1 |
| | | Practitioner safety checks | 1 | Imaging history check failure | 1 |
| Operator | 65 | Pre-exposure safety checks | 33 | Wrong exposure parameters | 14 |
| | | | | Inappropriate use of equipment | 8 |

| Tier 1 | | Tier 2 | | Tier 3 | |
|---|---|---|---|---|---|
| | | | | Wrong patient position/set-up | 6 |
| | | | | Wrong laterality/anatomy | 5 |
| | | Patient safety checks | 15 | ID error | 14 |
| | | | | Failure to check pregnancy | 1 |
| | | Exam authorisation | 9 | Wrong protocol/modality selection | 7 |
| | | | | Outside of guidelines | 2 |
| | | Post exam | 5 | Image transfer | 5 |
| | | Clinical history | 2 | Imaging history check failure | 2 |
| | | Referral information | 1 | Insufficient/inaccurate | 1 |
| Other | 76 | Equipment | 34 | IT error | 17 |
| | | | | Hardware | 8 |
| | | | | QC/Calibration issue | 7 |
| | | | | Local changes to protocol | 4 |
| | | Notification made in error | 14 | Below notification threshold | 14 |
| | | 10 x DRL/ deterministic | 15 | 10x DRL | 5 |
| | | | | Deterministic effects | 10 |
| | | Other | 6 | Other | 6 |
| | | Administrative error | 4 | RIS input | 3 |
| | | | | Other admin error | 1 |
| | | Volunteered | 3 | For shared learning | 3 |
| **Total** | **247** | | **247** | | **247** |

The most common type of error has continued to be where a patient has received an examination meant for another patient. However, this has decreased to 35% compared with 50% last year. The percentage attributed to referrer errors rose from 35% to 42% of the total while operator errors failing to correctly identify patients decreased from 16% to 6%.

It is not clear why the number of identification errors has decreased. One explanation may be the change in SAUE guidance. Last year, 61% of errors were from low-dose examinations such as plain film X-ray and mammography. Such examinations have a relatively high turnover of patients, which means more opportunity to make mistakes. CT also has the added checks when undertaking contrast questionnaires.

We received 34 notifications of equipment errors, the majority of which involved multiple patients. The types of errors ranged significantly and included:

- IT errors – such as RIS or PACS failures where images were either lost or were inaccessible in an emergency and needed to be repeated
- software errors – which included systems freezing or corrupting, which meant images were lost following an exposure
- hardware errors – where equipment itself failed, including detectors or tubes
- ancillary equipment errors – including ECG gating systems or injector pumps
- errors during calibration or handover – such as incorrect installations not picked up during QC or where changes in protocols were made with no associated handover.

## Inspections

In diagnostic imaging we carried out 10 planned inspections, including:

- 1 chiropractor
- 5 interventional/cardiology departments
- 4 general diagnostic imaging departments.

Six of these inspections resulted in enforcement action and therefore required a re-inspection at a later date. Of these, five related to poor documentation in relation to the employer's procedures and their review. This theme has been discussed in our previous two reports.

The publication of the new professional guidance, IR(ME)R: Implications for clinical practice in diagnostic imaging, interventional radiology and diagnostic nuclear medicine[8] provides useful examples of quality assurance processes for documentation and content for the employer's procedures. We will be looking for evidence of implementing such examples in the next phase of inspections.

Other than those examples included earlier in this report, findings included:

- failure to have audits to review regulatory compliance, or other clinical audit as required
- failure to have training records for radiologists or cardiologists where they are acting as operators, or not having them available for inspection
- lack of evidence for optimisation programmes.

## Key themes in diagnostic imaging

We have identified key themes from our work in diagnostic imaging, along with recommendations and examples. This year we concentrate on interventional radiology and cardiology following our thematic inspections, as well as learning for the new notification criteria.

## Interventional radiology/cardiology

Notification code 3 (interventional and cardiology) is one of the major changes in the SAUE guidance. We received many queries about this and provide some examples received in the first nine months to explain why we introduced the category.

Compared with other imaging modalities, IR(ME)R pathways in interventional radiology and cardiology are different as procedures and techniques are widely varied. Unlike a conventional X-ray or CT department, a wider range of healthcare professionals may be directly involved in undertaking the examination themselves including cardiologists, vascular surgeons, physiologists, and nurses, as well as radiographers and radiologists. Complex examinations, such as neurovascular and percutaneous coronary interventions are associated with high radiation doses, and some procedures can result in radiation injury from high skin doses or an increased risk of cancer.

Following the 'graded approach', we target our resources to areas with the highest risk, and we have decided to focus more of our attention to high risk examinations and their optimisation and audit.

### Diagnostic reference levels

There is a limited number of national and European DRLs that cover procedures performed in a relatively standardised way on a standard patient size.[9] National DRLs include procedures such as permanent pacemaker insertions, oesophageal stenting, and coronary angiography.

Despite this, our 2019 SAUE guidance introduced a new type of notification where a DRL is exceeded by 10 times during an individual case, even where there is no apparent procedural failure.

We set this level after consulting with medical physics experts who specialise in this field, allowing for a wide contingency to allow for the complexity of these procedures. We therefore set a multiplication factor at what we believe is sufficiently high to help indicate possible outliers. This was to gather information on:

- possible unoptimised examinations
- how dose audits are used
- methods for in-procedure dose monitoring and flagging of increasing doses
- how significant DRL breaches are identified, monitored and investigated.

### Deterministic effects

The specific safety guide from the International Atomic Energy Agency on radiation protection and safety in medical uses of ionising radiation mentions that radiation injuries should not be considered normal, and they can be reduced through good optimisation.[10] On this basis, we included this as a code even where there has been no procedural failure and the patient's dose may have been justified.

### Notifications under code 3 - interventional/cardiology

Between 3 June 2019 and 31 March 2020, we received 15 notifications linked to SAUE code 3. Five were in relation to the multiplication factor, and in 10 notifications deterministic effects were observed. All the deterministic effects were found following neurointerventional procedures and involved a small number of employers. We will look at these types of services in the next inspection programme to ensure that there are appropriate optimisation programmes in place.

The following examples show some good responses to investigations.

## Example where local diagnostic reference level was exceeded

We were notified of a permanent pacemaker insertion procedure that reached the notification threshold of 10x the local diagnostic reference level (DRL). The review of the examination found no procedural failure, but a number of factors meant the dose was significantly higher. These included the patient's high habitus and poor tolerance to sedation, which made them restless and uncooperative.

In response, the trust carried out a short audit of other recent procedures, which found that generally cases fell well within the local DRLs set by medical physics.

The local DRL set by the trust was considerably lower than the national level, at 100cGycm$^2$ compared to 700cGycm$^2$.

## Example of a voluntary notification

In this voluntary notification, a patient received an estimated 5x the local DRL in a complex CT cryoablation. Following the examination, the trust reviewed the procedure, which at the time was not considered to have had any procedural failings. However, on reflection, there were opportunities to reduce the patient's dose including:

- adjusting the scanning parameters (use a manual mA) and field size when they had noted the procedure was more complex than usual
- communicating with the radiologist during the procedure, as it was agreed that sometimes some of the scans would need to be a higher dose/quality, while at other times a lower dose/quality would be acceptable.

Following the investigation, the trust linked with another hospital trust to compare protocols and techniques to see if there is further opportunity to reduce patient doses in the future.

## Recommendations

**IR(ME)R employers must make sure that patient doses are as low as reasonably practicable. Reviewing optimisation programmes can help ensure that they demonstrate special attention to high-dose examinations and medical physics involvement. This may include reviewing:**



**Radiological equipment**

- **ensuring that equipment is working properly and delivering the appropriate exposures through an appropriate QA/QC programme**
- **regularly monitoring performance and risks from ageing equipment, adding risks to a risk register, more frequent testing, and implementing more specific performance criteria to trigger replacements**
- **reviewing equipment protocols and tailoring them where appropriate to cover the local range of techniques, including paediatric parameters.**

**Optimisation**

- **as a multidisciplinary team, altering techniques slightly without compromising the clinical objective, for example reviewing the number of frames per second, exposure factors or field size currently used (see the ICRP Publication 120 for more examples of optimising skin doses)[11]**
- **developing dose triggers during procedures that prompt operators to consider whether they can reduce doses or ask for assistance from colleagues, and to communicate properly during interventional procedures.**

**Monitoring and audit**

- **dose surveys, wherever possible**
- **developing skin dose triggers**
- **reviewing training and experience and comparing operators**
- **reviewing techniques of different employers through networks.**

### Accidental or unintended exposure

Historically, we have received a small number of notifications of procedural failures from interventional radiology or cardiology modalities (figure 6).

The type of incidents have involved:

- 10 wrong protocol/factors selected, most commonly due to using an incorrect frame rate
- 2 voluntary high-dose with no procedural failures
- 3 undeclared/unknown pregnancy.

**Figure 6: Number of interventional radiology and cardiology notifications received a year**

| | Interventional radiology: number of notifications | Cardiology: number of notifications |
|---|---|---|
| **2015** | 4 | 4 |
| **2016** | 4 | 4 |
| **2017/18** | 4 | 2 |
| **2018/19** | 3 | 1 |
| **2019/20** | 14 | 3 |

However, more high-risk incidents involved:

- using the acquisition pedal rather than fluoroscopy pedal throughout a procedure
- a consultant asking the cardiac physiologist to take on the role of the radiographer when they were not trained or entitled to do so
- a cardiologist carrying out an emergency procedure on a paediatric patient using an adult protocol when not entitled to do so.

These types of procedural failures and others such as wrong patient and wrong anatomy will continue to be notifiable under SAUE codes 1 or 2. However, code 3 has been designed to pick up a wider variety of incidents, which explains the higher number of notifications in interventional radiology received in 2019/20.

During the 2019/20 reporting period, we received four notifications involving a failure. Two related to equipment failures, one was below threshold and one related to the wrong exposure parameter being selected.

**Example of a notification based on deterministic skin effects**

A patient received two vertebral body tumour embolisations within nine days. The same operator had accidentally selected a cerebral rather than thoracic programme, which meant the patient received a higher dose than intended. The skin dose procedure triggered a patient follow-up, which found mild erythema (skin reddening). The exact dose, if the correct programme had been used, was unknown, but if the operator had selected the intended programme it was thought unlikely that the deterministic threshold would have been met.

In response, the trust audited patient records to ensure this was an isolated patient, as both cases involved the same operator. The trust also revised the safer surgery checklist to include a check of exposure factors and programmes selected.

# NUCLEAR MEDICINE

## Notifications in 2019/20

**We received 47 notifications in nuclear medicine from 3 June 2019 to 31 March 2020, which was 25% lower than the same period last year. These comprised 12% of the total number of notifications received, with 85% from NHS acute trusts.**

Of the 47 notifications, 40 originated from 28 individual NHS trusts, with the remaining notifications from just two independent healthcare employers. Over the reporting period, the greatest number of notifications received from a single employer was four.

We received the highest number of notifications in diagnostic imaging and PET-CT (figure 7). We continue to see a very low number of therapy notifications.

**Figure 7: Nuclear medicine notifications received by sub-modality, 3 June 2019 to 31 March 2020**

| Sub-modality | Number of notifications | % of notifications |
|---|---|---|
| **All diagnostic** | 43 | 91 |
| Diagnostic imaging | 17 | 36 |
| PET-CT | 17 | 36 |
| SPECT | 8 | 17 |
| In vitro | 1 | 2 |
| **Therapy** | 4 | 9 |
| **Total** | **47** | **100** |

### Types of error

We have not directly compared data with last year because of the significant change in number, notification criteria, and our internal criteria changes. Figure 8 shows the errors based on our new internal taxonomy.

As in previous years, most errors in nuclear medicine related to wrong patient referrals. Of the 19 notifications attributed to referrer error, 15 were requests for the wrong patient. The next most common source of reporting related to equipment issues, which accounted for 12 notifications (figure 8). We discuss equipment failure in more detail later in the report.

**Figure 8: Notifications received from nuclear medicine by detailed error type, 3 June 2019 to 31 March 2020**

| Tier 1 | | Tier 2 | | Tier 3 | |
|---|---|---|---|---|---|
| Referrer | 19 | Incorrect referral | 16 | Wrong patient | 15 |
| | | | | Wrong modality | 1 |
| | | Referral information | 2 | Failure to cancel a request | 1 |
| | | | | Insufficient/inaccurate | 1 |
| | | Other | 1 | Other | 1 |
| Practitioner | 1 | Incorrect justification | 1 | Protocol | 1 |
| Operator | 10 | Pharmaceutical administration | 3 | Wrong pharmaceutical | 2 |
| | | | | Wrong radioactivity | 1 |
| | | Exam authorisation | 2 | Wrong protocol/modality selection | 2 |
| | | Pharmaceutical preparation | 2 | Wrong radioactivity | 2 |
| | | Clinical history | 1 | Imaging history check failure | 1 |
| | | Pre-exposure safety checks | 1 | Inappropriate use of equipment | 1 |
| | | Other | 1 | Other | 1 |
| Other | 17 | Equipment | 12 | Other | 6 |
| | | | | IT error | 3 |
| | | | | QC/Calibration issue | 3 |
| | | Licensing | 1 | Lack of practitioner licence | 1 |
| | | Patient related | 1 | Other | 1 |
| | | Administrative error | 1 | Other | 1 |
| | | Other | 2 | Equipment | 1 |
| | | | | Other | 1 |
| **Total** | **47** | | **47** | | **47** |

# Inspections

We carried out three planned inspections of nuclear medicine departments in 2019/20, along with five reactive inspections in response to specific themes or concerns.

Of the reactive inspections, three related to licensing breaches. We focused on these following the change of licensing arrangements to IR(ME)R under the 2017 regulations. The remaining two were joint inspections with another radiation regulator, one in response to a brachytherapy incident and another following concerns about unsafe staffing levels, which resulted in enforcement action in relation to the study of risk for therapeutic procedures.

# Key themes in nuclear medicine

## Licensing

We continue to deal with incidents involving licensing breaches. Many of these were brought to our attention by the Secretariat of the Administration of Radioactive Substances Advisory Committee (ARSAC), and in some cases by informal contact from the employer.

### Example of a licensing breach

In one instance, we were made aware of a mobile PET-CT site where the practitioner was operating remotely, in breach of their licence conditions. On further investigation we found that the practitioner was working without a licence, as they mistakenly believed their certificate from another site was valid at the mobile PET-CT centre. However, under the transitional arrangements from MARS1978 to IR(ME)R17, certificates are only valid at the site for which they were issued. In this case, 55 patient examinations were unjustified because of this oversight, and two scans were not included in the employer's licence.

The employer carried out a detailed audit to identify all scans affected, and both internal and external practitioners reviewed these examinations to ensure that they were appropriately justified. The outcomes of the investigation included a new process for managing licensing arrangements, as well as establishing PET-CT specific radiation protection meetings and implementing an ongoing audit to ensure justification falls within the site's licensed examinations.

## Licensing webform

Breaches have often come to light following an ad-hoc review of licensing arrangements; in many cases there was no process to routinely manage licences. Many employers also want to tell us about breaches to enable open and transparent governance. In response, we launched a webform for breaches of IR(ME)R licences to enable employers to notify us. This provides an appropriate channel for these non-statutory notifications outside of the SAUE process. It enables us to gather information and identify themes around licence management – not to get an overall picture of compliance with Regulation 5, but to understand better record-keeping and data integrity.

## Recommendation

**It is the responsibility of both the IR(ME)R employer and the practitioner to ensure that appropriate licences are in place, as required by Regulation 5. Individual duty-holders have a professional responsibility under Regulations 10(1) and 11(1) to ensure that the employer's procedures in relation to licensing requirements are adhered to, and that the practitioner holds a licence to enable them to justify procedures involving the administration of radioactive substances. When entitling new practitioners, employers must review each candidate's licensing and certification, taking into consideration that certificates are site-specific and not transferable.**



## Update to SAUE guidance on nuclear medicine therapies

Following feedback from employers, the updated guidance on SAUE includes changes to nuclear medicine therapies. These are now categorised distinctly from external beam radiotherapy and brachytherapy, and includes a separate category for selective internal radiation therapy (SIRT) procedures.

## Equipment failure

A number of notifications relate to failure of equipment, and in many cases this has been attributed to the reduced reliability of ageing gamma cameras. Financial pressures mean that imaging systems are more often used past their planned end of life, and we have found this to be more prevalent in nuclear medicine departments.

In all cases, multiple patients had already been injected when the camera failed, leading to a notifiable incident under SAUE. We have also had a number of reports around failures of hybrid equipment, particularly PET-CT systems, as the following examples show.

**Example of risk management of ageing equipment**

A trust with two main hospital sites had similar intermittent equipment faults, as CT scanner components occasionally failed on both SPECT cameras, which were unrepairable. After a risk assessment, the trust's nuclear medicine team, including an IR(ME)R practitioner and medical physics expert, concluded that the successful scanning of the majority of patients outweighed the relatively low dose and frequency of unintended exposures.

Both cameras were approximately 14 years old and were to continue in clinical use with more maintenance, QA and monitoring arrangements, while waiting for a business case to be approved for a single replacement machine. A new camera was delivered some months later, but before it arrived 16 patients were exposed unintentionally.

**Example of the impact of nuclear medicine equipment failure**

The logistics of nuclear medicine means that several patients can often be administered with radioactive material within a short time, particularly if having the same examination. If there is an equipment fault, multiple patients are likely to be affected. In this case, a breakdown meant that five cardiac patients, who had already been injected, were not able to be scanned and so needed subsequent repeat appointments. The equipment was ageing and was on the risk register, but had no previous significant fault history. The fault was successfully repaired and a business case for a new machine subsequently approved. In the meantime, the camera was checked daily before patients were injected.

Both these incidents demonstrate how ageing and faulty equipment needs ongoing monitoring and risk assessment, as it can have a significant impact not just on unintended exposures to patients, but also on diagnostic services more generally to local populations. Nuclear medicine providers need to manage such risks proactively, with essential equipment replacement programmes that include contingency planning and flexibility around service support, maintenance, QA programme and patient scheduling.

## Recommendations

**Licensing:**

- **Nuclear medicine departments should ensure that they maintain a process for managing licences and certificates to administer radioactive substances.**
- **Under the transitional arrangements, practitioner certificates are only valid at the site for which they were issued, for the same scope and purpose, as set out in the ARSAC Notes for Guidance. Employers should ensure they carefully review licences of practitioners transferring from other sites.**
- **Both the employer and practitioner are responsible for ensuring that appropriate licences are in place. When entitling new practitioners, employers must review each candidate's licensing and certification. Where gaps in licensing arrangements are identified, departments should consider notifying CQC using the webform, to demonstrate good governance and to aid in thematic analysis.**

**SAUEs in nuclear medicine therapies:**

- **Departments should be aware of the change in notification threshold for SIRT procedures and report any incident where the administered activity falls outside the threshold, as well as all clinically significant accidental or unexpected exposures.**
- **Departments should consider reporting near-miss and other non-notifiable incidents to improve shared learning.**

**Equipment failure:**



- **To reduce the chance of significant unintended exposures, equipment that is still in clinical use towards, and past, its end of life should have extra scrutiny. This may include more frequent or specific quality control tests and regular routine maintenance, as well as adding to a risk register.**
- **Recurrent faults with hybrid equipment should be addressed with the equipment manufacturer first, but employers should also consider reporting persistent issues to the Medicines and Healthcare products Regulatory Agency.**
- **As well as daily quality control checks, medical physics experts should review the frequency and effectiveness of routine checks where equipment has known issues. Systems with a history of unreliability should be under increased scrutiny, in terms of both quality control and routine maintenance, to ensure that they remain fit for their clinical purpose.**

# RADIOTHERAPY

## Notifications in 2019/20

**We received 113 radiotherapy notifications in 2019/20, representing 28% of all notifications received. Of these, 96% were from NHS acute trusts.**

There has been a small decrease in the number of notifications this year, with external beam therapy and planning and verification imaging contributing 97% of all notifications received (figure 9). Many of these errors related to delivering radiotherapy treatment, specifically geographical misses due to shift errors (figure 10). Treatments and their associated imaging requirements are becoming more complex, meaning this will likely continue to be an area of high risk.

Planning and verification imaging made up nearly half of all radiotherapy notifications. Of these 55 notifications, around half related to selecting the incorrect verification imaging preset. This number is expected to decrease next year as the requirements for notification have been amended to reflect the level of risk, as the dose given during verification imaging is minimal compared with the total dose delivered.

**Figure 9: Radiotherapy notifications received by sub-modality, 2019/20**

| Sub-modality | 2019/20 | |
|---|---|---|
| | Number of notifications | % notifications |
| External beam therapy | 55 | 49% |
| Planning and verification imaging | 55 | 49% |
| Brachytherapy | 3 | 3% |
| **Total** | **113** | **100%** |

### Types of error

We have not directly compared with last year's data because of the significant change in number, criteria, and our internal criteria changes. Figure 10 shows the errors based on our new internal taxonomy.

**Figure 10: Notifications received from radiotherapy by detailed error type, 3 June 2019 to 31 March 2020**

| Tier 1 | | Tier 2 | | Tier 3 | |
|---|---|---|---|---|---|
| Referrer | 13 | Incorrect referral | 12 | Premature referral | 6 |
| | | | | Not in accordance with guidelines | 3 |
| | | | | Wrong treatment protocol/dose | 3 |
| | | Other | 1 | Administrative error | 1 |
| Practitioner | 5 | Incorrect justification | 3 | Target volume/outline error | 2 |
| | | | | Justify/authorise wrong plan/protocol | 1 |
| | | Other | 2 | Patient related | 1 |
| | | | | Other | 1 |
| Operator | 71 | Treatment | 55 | Verification - protocol selection error | 24 |
| | | | | Geographical miss - shift error | 11 |
| | | | | Geographical miss – online matching error | 7 |
| | | | | Online matching error | 7 |
| | | | | Geographical miss – verification image | 3 |
| | | | | Patient ID/queuing error | 1 |
| | | | | Application/source error - brachytherapy | 1 |
| | | | | Wrong applicator cut-out filter | 1 |
| | | Planning | 10 | Calculation/checking/data entry error | 6 |
| | | | | Wrong image/patient data used | 4 |
| | | Pre-treatment | 4 | Wrong scan protocol selected | 4 |
| | | Other | 2 | Equipment | 2 |
| Other | 24 | Equipment | 16 | IT error | 12 |
| | | | | QC/Calibration issue | 3 |
| | | | | Verification – protocol selection error | 1 |
| | | Patient related | 2 | Other | 2 |
| | | Volunteered | 1 | Other | 1 |
| | | Other | 4 | Other | 4 |
| | | Notification made in error | 1 | Other | 1 |
| **Total** | **113** | | **113** | | **113** |

# Inspections

In 2019/20, we carried out five inspections of radiotherapy departments, including four planned and one reactive inspection.

Some findings from inspections mirrored those seen in other modalities, such as schedule 2 procedures not reflecting local practice, incomplete equipment inventories and out of date policies and procedures. A study of risk as part of a QA programme for radiotherapeutic exposures, which is required to comply with Regulation 8(2), is still lacking at some trusts despite radiotherapy departments generally having well-established risk assessment processes.

Several inspections highlighted concerns about staffing, particularly the shortages in radiotherapy physics and clinicians. The trusts advised that the barriers to recruitment were not financial but related to the availability of candidates. Trusts had recognised this issue and were taking steps to address it such as increasing the use of advanced practitioner radiographers to carry out some tasks to reduce the workload of clinicians. However, it remains an area of concern.

# Key themes in radiotherapy

## Referral, pre-treatment and planning errors

We received a significant number of notifications of errors in referral, pre-treatment and planning in 2019/20. The causes included:

- referring for radiotherapy before all the required diagnostic information was in place to support the referral
- inadequate communication of change to treatment intent
- incorrect information held in the quality system, leading to applying the wrong prescription.

### Example of a referral error

A patient's treatment had been planned but before the first fraction, the clinician decided not to proceed because of further information regarding histology. The change in intent was documented in the trust's clinical notes system. However, it was not adequately communicated to the radiotherapy team, so the appointment for treatment was sent out to the patient. They attended for treatment, but as staff had not seen the annotation on the clinical notes system, they were treated in error.

Causative factors identified that the clinician had sent an email cancelling treatment to a specific person, but this person was on annual leave. In response, the trust has set up a generic email account that several people can access to notify changes in treatment intent.

### Example of a planning error

A patient had palliative treatment planned to the lung and mediastinum. The dose prescribed was higher than normal and not the standard dose and fractionation, although it was included within clinical protocols for the trust and in guidelines from the Royal College of Radiologists (RCR).

Although the dose and fractionation were included in the trust's quality system, it did not state that a two-phase treatment would be needed to shield the spinal cord, which was contained in the field. Treatment was v-sim planned and delivered with the spinal cord in the field for all fractions. The patient's spinal cord received 42Gy in total, whereas RCR guidelines state a maximum dose of <36Gy.

The error was identified when another patient was prescribed the same dose/fractionation and a staff member queried if the shielding was needed as this was the process when previous patients had been simulator planned. This prompted a review of all patients who had received this treatment. The investigation identified that when treatment protocols were updated a few years previously, the requirement for a two-phase approach for this dose and fractionation had been omitted in error.

The trust's actions taken in response included:

- Reviewing all information held in clinical protocols against source data
- Changing practice so that all patients receiving this dose would be planned using the trust's planning system, to enable a review of the dose to organs at risk.
- Updating the training for v-sim staff to highlight organs at risk of a dose.

The trust's investigation showed how much staff rely on clinical protocols. This highlights the importance of ensuring that the data held in the quality system is rigorously reviewed before being added to the trust quality system.

## Verification imaging

Of the verification imaging notifications received, half related to the selection of the imaging preset or modality (for example, a pelvis imaging preset selected for a patient needing head and neck treatment, or a CBCT given instead of the intended kV modality).

### Example of a verification preset selection error

Although many centres have synergistic record and verify (R&V) and imaging systems, machines in some centres need an imaging preset to be selected manually. A recurrent theme in notifications is when an operator inadvertently changes a preset selected from a drop-down menu, often after the pause and check process. This means that another preset is loaded so the patient receives an unintended dose, or the image can't be used.

Some centres considered disabling the thumbwheel to stop this error from happening, but this significantly impairs the functionality of image matching, therefore this option was discounted.

To address the issue, centres:

- re-ordered the imaging presets so that lower doses are grouped together, (for example, grouping pelvis presets together and not next to H&N presets), which minimises the difference in dose if the thumbwheel is touched inadvertently
- changed the process so that the preset is the last thing checked before conducting the verification image.
- educated staff about the issue and raise awareness of the possibility of the error.

## Treatment

Geographical misses, either partial or full, comprised 19% of notifications. Several root causes included poor recording or lack of appropriate localisation information, staffing issues and problems relating to COVID-19 and its associated pressures. One incident identified that the delay between patient mark-up and treatment had significantly contributed to a total geographic miss for a skin electron treatment. In this case, the normal 'one stop shop' approach for skin apposition treatment had been paused because the trust's machine replacement programme meant staff were working extended hours and under pressure. This service has now been reinstated to improve the patient experience and reduce the risk of this error recurring.

Skin apposition electron treatments continue to be a recurring theme in notifications, with errors relating to partial or full geographic misses. Reviews identify the main causative factor as poor recording and availability of setup information for patients. Areas for improvements included:

- the use of photographs and acetates with orientation marks
- anatomical landmarks recorded for every patient to ensure correct treatment
- associated protocol change and education.

We received several notifications relating to incorrect matching to anatomy, causing a partial geographic miss. Common causes included:

- imaging fields that do not include unique anatomy, for example vertebrae only
- insufficient imaging field size
- staff with insufficient experience in online image matching

Actions to address this included:

- creating an imaging field to include anatomy that would allow a surrogate match
- increasing size of imaging field
- additional imaging training for staff for online image matching
- using imaging specialist for single treatments

Another cause of geographic miss affecting multiple patients at different trusts related to incorrect data entry for a kV verification field, which would result in the machine applying moves in the wrong direction once an image match had been achieved.

### Example of a geographical miss

Some R&V systems create a field to deliver a kV image. The acquisition of the field is defined using an XVI preset from a drop-down menu, which defines the gantry position that the kV image will be acquired with. Operators will then move the machine to the correct gantry angle (GA) before imaging. The planar kV image is then compared to the digitally reconstructed radiograph (DRR) in the matching software. The source angle (SA), which is manually inputted, is then used to interpret the results of the match and generate the required shifts to correct the patient setup.

R&V systems need a manual override if the GA is out of tolerance by a set margin, but some R&V systems do not verify that the SA is consistent with the XVI preset. This means that the SA can be input incorrectly, and an image taken without any warning to operators. As the SA is used to generate shifts, this means that moves can be made in the wrong direction for example, if the SA is set to zero and the images were taken at 180 degrees then a corrective couch shift left/right would be reversed, therefore increasing the set-up error, not correcting it. When taking a lateral image this could also mean a left/right shift would be implemented as opposed to an anterior/posterior shift.

The errors in different trusts were consistently missed due to several factors:

- a lack of awareness of the impact of an incorrect SA
- shifts are often required in palliative treatments and it is common for patients to move during treatment because of pain, therefore needing reversal of moves
- some departments do not routinely re-image after a shift unless it is greater than a set tolerance, e.g. >1cm, therefore the shift errors were not seen.

The clinical impact in most cases was negligible, as treatments using this imaging modality often have large treatment margins and would therefore absorb a shift error to some extent. However, some patients received treatment >1.5cm from the intended location.

Actions taken to address the issue included educating all staff on the importance of checking the SA and reviewing all protocols and procedures to ensure they documented the importance of the correct SA. The trusts also advised that planned upgrades to the R&V systems will mean that transfer of information such as SA will be automated.

## Recommendations



- **The verification imaging preset selection process should be automated. If this is not possible, employers must mitigate the risk of inadvertently selecting incorrect pre-set or operator input error.**
- **Verification imaging fields should contain sufficient anatomy to enable accurate matching. Using larger fields containing additional surrogate anatomy is recommended particularly for sites where incorrect matching is likely, such as treatments to the spine.**
- **Skin apposition treatments should always use photographs giving both close-up and wide views in conjunction with anatomical landmarks.**
- **The time between clinical mark-up of fields and treatment should be kept to a minimum when no permanent marks are applied.**

# CQC's WIDER IR(ME)R ACTIVITY IN 2019/20

## International Atomic Energy Agency Integrated Regulatory Review Service mission to the UK

The Minister for Business, Energy and Industrial Strategy invited the International Atomic Energy Agency (IAEA), on behalf of the UK government, to carry out a peer review of the UK's regulatory infrastructure for nuclear, radiation, radioactive waste, and transport safety. The purpose of this mission was to evaluate the UK's regulatory framework for nuclear and radiation safety against the IAEA safety standards.[12]

This involved government bodies, such as the Department of Health and Social Care, advisory bodies, such as Public Health England, as well as 15 regulatory bodies including CQC, and took place over two weeks in October 2019. The review used methods including a self-assessment, interviews with representatives from CQC and observing an IR(ME)R inspection.

The report of the review, published 9 July 2020, detailed the findings in relation to each standard and gave recommendations and suggestions for improving our regulatory oversight.[13]

The vast majority of the recommendations for CQC had been previously recognised, so work had already started in identifying improvements.

One area from the report that we have already addressed is the cooperation between the regulatory bodies. We already had existing relationships with the Health and Safety Executive, the Environment Agency and the other devolved administrations for health. But, through the peer review process and the subsequent post review work, we have developed improved working relationships. This has increased communication and sharing of internal practices and intelligence, as well as raising the possibilities of joint inspection and regulatory processes.

Other actions in relation to the recommendations are currently being scoped. These will include defining a 'graded approach' and reviewing our internal resources.

A follow-up peer review to observe the actions that the UK has undertaken is planned for the next three to four years

## Committees and liaison

Our IR(ME)R team continues to provide support and involvement in several committees and groups across both imaging and radiotherapy. This includes liaison with other agencies and regulatory bodies.

- Medical Radiation Liaison Group (MRLG), which includes regulatory and government bodies involved in medical exposures across the UK and is chaired by Public Health England (PHE).
- Clinical Imaging and Radiotherapy Boards that involve the professional bodies in England such as the Society of Radiographers (SoR), the Royal College of Radiologists and the Institute of Physics and Engineering in Medicine (IPEM).

- Special interest groups led by the British Institute of Radiology and IPEM, which include radiotherapy, nuclear medicine, diagnostic radiology and radiation protection
- regular meetings with SCoR, IPEM and PHE to discuss topical issues and contribute to working parties.

## Heads of European Radiological Competent Authorities

Despite the UK exiting the European Union, as the enforcement body for England, CQC considered maintaining a role within working parties at Heads of European Radiological Competent Authorities (HERCA) meetings.

HERCA is a voluntary association in which the Heads of Radiation Protection Authorities work together to identify common issues and propose practical solutions. HERCA is working on topics generally covered by provisions of the EURATOM Treaty. The programme of work of HERCA is based on common interest in significant regulatory issues.

The most recent meeting was cancelled due to COVID-19, but virtual meetings and correspondence have continued. When the BSSD was transposed in 2017, HERCA were predominantly focused on implementation and transposition across nations. The work for 2020/21 concentrates on embedding the new regulations and improving the understanding across Europe of the role of justification and clinical audit. As part of the clinical audit working party, CQC has written a paper on the fundamental differences between clinical and regulatory audit, which is a common misunderstanding in some European countries. England has a well-established clinical audit framework within healthcare, so CQC is also now an integral part of the advisory board for the QuADRANT project.

The project is designed to be a constant improvement in quality and safety of radiology, radiotherapy and nuclear medicine through clinical audit, which the European Society of Radiology (ESR) is coordinating in consortium with the European Association of Nuclear Medicine (EANM) and European Society for Radiotherapy and Oncology ESTRO. A workshop will be held in December with member states.

# NEXT STEPS

We have started our programme of planned inspections, which includes departments across all three modalities. We will also be focusing on several key topics, including:

- provision of nuclear medicine and radiotherapy services in the independent health sector
- nuclear medicine therapy services
- neuro-interventional service inspections
- further collaboration with other regulators in reviewing areas of mutual interests
- the role of assistant practitioners on mobile mammography units, alongside NHS Breast Screening Programme and the Society and College of Radiographers
- responding to the COMARE report on dual energy X-ray absorptiometry (DXA)
- developing an employer information request process to support our risk-led inspection programme
- reviewing the data we gather and how it can supplement our inspection programme
- responding to the recommendations in the report of the IAEA Integrated Regulatory Review Service (IRRS) mission.

# APPENDIX A: TYPES OF MEDICAL EXPOSURE

**Beam therapy** is radiotherapy where an 'external' beam of high energy radiation is aimed at the cancer or diseased anatomy. It is typically given as a number of short daily treatments using a machine called a linear accelerator (linac). In all therapy a high dose of radiation is targeted on the tumour but adjacent healthy tissue receiving a small amount of radiation which can be tolerated.

**Brachytherapy** and **nuclear medicine therapy** are where radioactive source(s) or material are applied directly to an affected area whether internally or externally. These therapies involve the insertion of small radioactive 'seeds' into the cancer, placing radioactive materials (within tubes) directly onto the tumour for a set length of time or injecting radiopharmaceutical which will concentrate naturally in the target organ.

**Computed tomography (CT)** is a scan that combines a series of X-ray images taken from different angles around the body to create detailed cross-sectional images (slices) of the inside of the body.

**Coronary catheterisation** refers to the imaging of blood vessels in the heart for both diagnostic and interventional purposes. These procedures can be used in emergencies, such as in a heart attack, or to look at unusual test results, such as stress tests of unexplained heart failure. Throughout this report we use the term **Cardiac** to describe such procedures.

**Dual energy X-ray absorptiometry (DXA)** is a special type of X-ray scan that measures bone mineral density (BMD).

**Fluoroscopy** is similar to an X-ray 'movie'. The images are transmitted to a TV-like monitor in real time so that the body part and its motion can be seen in detail. Fluoroscopy is used to look at many body systems, including the digestive, urinary and reproductive systems and provides information on their function as well as anatomy.

**Interventional radiology** refers to a range of techniques that rely on the use radiological image guidance (fluoroscopy, ultrasound, computed tomography or magnetic resonance imaging) to precisely target therapy. Throughout this report we use this term to describe fluoroscopy-guided interventional radiology (imaging of the blood vessels to look for abnormalities with the use of various contrast media).

**Mammography** uses X-rays to examine the breast for diagnosis and screening. The goal of mammography is the early detection of breast cancer, through the National Health Service Breast Screening Programme, or assessing lumps through symptomatic mammograms.

**mSv** milli-sievert is the radiation dose unit used to measure effective dose.

**Nuclear medicine (NM)** uses small amounts of radioactive material to diagnose, determine the severity of or treat a variety of diseases, including many types of cancer and heart disease. PET-CT (Positron emission tomography-computed tomography) and SPECT CT (Single-photon emission computed tomography) are similar but they combine the NM examination with a CT scan.

**Plain film X-rays** are two-dimensional pictures of the inside of the body. They are good at looking for problems in bones, teeth, the chest and some soft tissue areas, such as the abdomen, and are usually the first (and sometimes only) diagnostic imaging used to diagnose a disease or condition.

# APPENDIX B: RECOMMENDATIONS FROM INSPECTIONS 2019/20

| Inspection | Regulation | Recommendation |
|---|---|---|
| **Chiropractor - May 2019** | 6(1) Schedule 2 | The employer must ensure there is a full list of procedures in place as required by Schedule 2. The procedures should also be reviewed to ensure they reflect practice. |
| | 6(5)(a) | The employer must establish recommendations concerning referral guidelines for medical exposures, including radiation doses, and ensure that these are available to the referrers. |
| | 6(5)(c) | The employer must make diagnostic reference levels available to the operators. |
| | 14(3)(b) / 15(1)(a) | The employer should seek advice from their medical physics expert around the quality assurance testing programme for imaging equipment. |
| **Radiotherapy - May 2019** | 6(1) Schedule 2 | The trust should ensure that it reviews the level of detail required within existing procedures and work instructions to ensure that staff are supported adequately when making relevant enquiries with patients. |
| **Interventional radiology - June 2019** | 17(4) | The trust must ensure that they keep up-to-date training records for all IR(ME)R practitioners and operators. |
| **Interventional radiology - July 2019** | 6 | The governance structure should be clearly documented to reflect where sub committees feed into the radiation protection committee as well as trust wide structures. |
| | 6(1) Schedule 2(c) | The pregnancy procedure should be reviewed to ensure it reflects clinical practice. |
| | 15(2)(d) | The equipment inventory must include year of manufacture. |
| **Radiotherapy - July 2019** | 6(1) Schedule 2 | The trust should ensure that it reviews the document control cycle and the arrangements for sign-off, including the employer's procedures and dose information for operators. |
| | 6(1) Schedule 2 | The trust should re-introduce photographic cameras to assist in patient identification arrangements as had been set out in its procedures. |
| | 8(2) | The trust should ensure it develops a 'study of risk' in accordance with this regulation. |
| | 15(2) | The trust should ensure it maintains an inventory of equipment in line with the detail required in this regulation |

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| | | and include the treatment planning and oncology management systems. |
| **Diagnostic imaging - August 2019** | 6(2) | Schedule 2 procedures require a full review to ensure that they are locally reflective. This must include a clear definition of the roles and scope of responsibilities for each duty holder. |
| | 6(5)(a) | Referral guidelines must be made available to all referrers requesting imaging from the trust. |
| | 12 | A full optimisation programme must be established, taking into account the recommendations of COMARE report 16. |
| | 15(3)(b) | The backlog of physics equipment testing must be addressed. |
| **Interventional radiology – August 2019** | 7 | Audits of regulatory compliance should be performed on a routine basis. Where concerning findings are identified, re-audit should be completed as a matter of priority. |
| | 8(4)(iii) | Incident reports must consist of a detailed investigation of the circumstances of the exposure and the dose received. Where applicable, the enforcing authority should be notified of the outcome of the investigation and any corrective measures adopted. |
| | 15(3)(b) | The backlog of level B testing should be addressed. Level A testing should include comments on remedial actions taken. |
| **Nuclear medicine – September 2019** | 6(5)b | Written protocols must be in place for all standard nuclear medicine examinations and treatments and must be reviewed and revised in accordance with the documented quality assurance programme. |
| | 14 | The appointment and involvement of an MPE for nuclear medicine must be sufficient to meet the responsibilities and role under this regulation, taking account of the level of support that was stated within the application for the employer licence. |
| | 15(3)b | Routine performance testing of nuclear medicine equipment needs to be carried out as defined in the quality assurance programme in line with recommended standards. |
| | 17(4) | An up-to-date record of practitioners and operators training, including any competency or practical training on equipment, must be available for inspection. |
| **Radiotherapy - October 2019** | 6(1) Schedule | Review the frequency of the QA document control cycle alongside professional guidance. |
| | 6(1) Schedule 2 | Review the content of procedures and work instructions to ensure they clearly demonstrate the responsibilities of duty holders. |
| | 8(2) | Develop a quality assurance procedure which includes a study of risk of accidental and unintended exposures. |

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| | 15(2) | Maintain an inventory of equipment in line with the detail required in this regulation and include the treatment planning and oncology management systems. |
| | 17(1) | Review arrangements for pregnancy testing to ensure that staff carrying out this responsibility are adequately trained to interpret the results. |
| **Interventional radiology - October 2019** | 8(3) | Establish a more robust system for the analysis of incidents involving radiation. |
| | 14(2)(b) | Review the input of the medical physics expert to ensure sufficient involvement. |
| | 15(6)(a) | Put measures in place to manage the performance and reliability of ageing interventional radiology equipment. |
| **Nuclear medicine – November 2019** | 6(5)(b) | Establish a formal quality assurance programme for procedures and policies to ensure that they comply with IR(ME)R. |
| | 6(5)(c) | DRLs must be regularly reviewed to ensure they reflect clinical practice. |
| | 15(2) | The equipment inventory for Nuclear Medicine should be amended to include the date of manufacture of each item. |
| **Diagnostic imaging - November 2019** | 6(2) | Schedule 2 procedures require a full review to ensure that they are locally reflective of the work carried out at the trust. This must include all schedule 2 employer's procedures. Procedures(c), (d), (g), (i), (k), (l), (m) and (n) especially must be strengthened. |
| | 7 | The employer's procedures must include provision for the carrying out of clinical audit relevant to IR(ME)R regulations. |
| | 12 | A programme of dose/image quality optimisation must be established to support interventional radiology and cardiology exposures. |
| | 12(8)(c) | Special attention should be paid to high dose procedures and consideration should be given to a more robust procedure to manage high skin doses in cardiology |
| | 15 (2) | The inventory of radiological equipment must be kept with all required fields. |
| | 15(3)(b) | The backlog of physics equipment QA testing must be addressed. The trust should also review the level A tests undertaken by radiographers and how those results of those tests are compared previous results to assure consistency. |
| | 17(1) | The employer should review the practical training needs for interventional radiologists and cardiologists acting as operators to ensure they are adequately trained to operate their respective equipment. |
| | 17(4) | Training records must be kept and available for inspection. |

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| **Diagnostic imaging – January 2020** | 6(5) | The trust must make referral guidelines available to all referrers. |
| | 6(1) Schedule 2(i) | A procedure for the provision of information to patients relating to the benefit and risks of their exposures must be written and ratified. |
| | 7 | The trust should develop a clear process for management of audits within radiology. |
| | 15(2)(d) | The equipment inventory must include the serial number, years of manufacture and installation. |
| **Radiotherapy – February 2020** | 6(2) | The trust must review the organisation and accessibility of protocols to enable duty holders to locate all essential documents more readily. |
| | 6(4) | The trust must maintain clinical treatment protocols in accordance with the frequency set out in local policies. All hard copy versions in the department should be reviewed to ensure the most recent version is displayed. |
| **Interventional radiology - February 2020** | 6(5) | Regular review of diagnostic reference levels must be undertaken, with specific attention paid to optimisation. |
| | 15(2) | The equipment inventory must be updated to include the fields specified in the regulations. |
| | 17(4) | Up-to-date records of all relevant training of practitioners and operators must be developed. |

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## How to contact us


| | |
|---|---|
| Call us on: | 03000 616161 |
| Email us at: | enquiries@cqc.org.uk |
| Look at our website: | www.cqc.org.uk |
| Write to us at: | Care Quality Commission<br>Citygate<br>Gallowgate<br>Newcastle upon Tyne<br>NE1 4PA |

Follow us on Twitter: @CareQualityComm


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