

IR(ME)R annual report 2018/19

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

December 2019

Care Quality Commission

Our purpose

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.

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. 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 providers to ensure compliance with the regulations.

Under IR(ME)R 2017, the definition for making statutory notifications of incidents has changed from 'much greater than intended' to 'significant accidental and unintended exposures'. We published guidance on this in June 2019.

Key findings in 2018/19

The use of diagnostic imaging and nuclear medicine has continued to grow. In 2018/19, 43 million diagnostic imaging examinations were carried out on NHS patients in England, of which almost 30 million used ionising radiation. Activity across all types of imaging grew by just under 2% compared with the previous year.

Statutory notifications of errors: 1 April 2018 to 31 March 2019

We received a total of 1,009 notifications during the year, which was comparable with the previous year (969). Although notifications relate to incidents where there is risk of harm, the majority do not result in harm to patients.

Diagnostic imaging

- 796 notifications – an increase of 4% over the previous year. These comprised 79% of all notifications received in both 2017/18 and 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 50% of all diagnostic imaging errors resulting from referrers failing to refer the right patient or operators failing to actively identify their patients.

Nuclear medicine

- 75 notifications – an increase of 10% over the previous year. These comprised 7% of all notifications received.
- The vast majority of notifications were from diagnostic nuclear medicine (95%).
- Errors related to patient identification, failure to cancel examinations that were no longer required, and administrations of the incorrect radioactive medicinal product. This was comparable with 2017/18 and previous years.

Radiotherapy

- 138 notifications – an increase of four notifications over last year. These comprised 14% of all notifications received.
- There was a small increase in the number of radiotherapy imaging notifications (including pre-treatment and verification imaging), but a decrease in treatment notifications compared with the previous year.
- The most common errors were around referrals, where a lack of communication and adequate checking contributed, as well as distractions and environmental factors.

Under the new guidance and notification criteria we are expecting to receive fewer notifications – particularly from diagnostic imaging. This is because these incidents are lower in dose and no longer reach the threshold criteria to notify us.

In this reporting period, we carried out 25 inspections under IR(ME)R – either planned inspections as part of a programme, or focused inspections in response to concerns or high-risk notifications. IR(ME)R inspectors have also contributed to updating the inspection frameworks for acute hospital and dental provider inspections under the Health and Social Care Act 2008.

Enforcement action

A common factor that contributes to poor compliance with the regulations is an inadequate governance framework surrounding radiation protection. We issued Improvement Notices under IR(ME)R to eight NHS trusts through both our programme of planned inspections and focused visits.

Most enforcement action was taken in response to failures relating to employer's procedures, where providers breached Regulation 6(1)(a) by not having a full set of procedures in place, failing to make these available to staff or failing to keep them quality assured. We also took enforcement action where providers failed to maintain a quality assurance programme of equipment including regular testing, and where they failed to keep up-to-date records of this.

The new SAUE guidance introduced timeframes for making notifications and submitting details of investigations. Under Regulation 8(4), we now have the power to take enforcement action against providers who do not provide information about a notifiable incident within 12 weeks.

Action for providers

We are still seeing too many errors resulting from inadequate checks. All IR(ME)R duty holders need to be vigilant, follow procedure and adopt safe practice, including making multi-point checks at all stages. Based on our findings, we recommend some actions for providers to improve both compliance with the regulations and the quality and safety of care for patients:

Governance

- **Review the scheme of delegation for tasks relating to radiation protection, for example ratifying procedures.** This should include all services that use ionising radiation, particularly departments that do not have extensive understanding of the regulatory requirements, such as those outside of radiology departments.
- **Enable departments to feed into more senior committees.** This helps to ensure that risks and assurances are shared and acted on.

Employer's procedures

- **Review the IR(ME)R employer's procedures to ensure they provide the appropriate information to enable staff to follow them.** It is useful to have several separate procedures or standard operating procedures for different services. For example, staff working in nuclear medicine or interventional radiology departments have different practices around justification and consent to those of plain film departments.
- **Tailor the IR(ME)R employer's procedures to the intended clinical department and its specific work activities.** Although there is a requirement to have all procedures in place, lengthy documents covering an entire provider do not always reflect local practice, so it is useful to have a shorter, more concise practical version for some areas and staff.

Equipment

- **Check the age profiles and performance of equipment to reduce the risk of incidents.** Regulation 15 sets out the duty to improve inadequate or defective performance of equipment. If it is not possible to replace ageing equipment, this should be flagged on a local risk register to manage it appropriately.

Working practices

- **Consider carrying out a more detailed investigation of the circumstances for repeated types of error.** A review of working practices could include:
 - environmental factors such as distractions, poor design or lack of available equipment
 - task factors such as the appropriateness of procedures, understanding or complacency of staff
 - human factors, such as working automatically without proper attention, or ineffective communication
 - staffing factors such as ineffective leadership, fatigue or overload, or inappropriate skill mix.
- **Before administering nuclear medicine, a multi-point check should include a check against the original request to ensure the correct scan has been selected.** All IR(ME)R duty holders need to be vigilant, follow procedure and adopt safe practice at all stages of the nuclear medicine pathway.

Licence applications

- **Involve a multidisciplinary team when applying for site licences for radioactive substance administrations.** Management checks and ongoing audit are essential to ensure the licence covers all existing clinical practice and to accommodate any relevant departmental changes and service developments. A written procedure, including the line of accountability to the employer, helps staff and management.

INTRODUCTION

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.¹ The regulations state that medical exposures such as those used in diagnosis, treatment, research and screening, and non-medical exposures using medical radiological equipment, need to be individually justified and optimised.

The previous regulations (IR(ME)R 2000 (as amended)) were revoked in February 2018 and replaced with IR(ME)R 2017² to satisfy Council Directive 2013/59/EURATOM.³ This introduced a change of definition for statutory notifications from 'much greater than intended' under IR(ME)R 2000 to 'significant accidental and unintended exposures'.

This report is the first covering a full year's activity under IR(ME)R 2017, providing analysis of statutory notifications and inspection activity from 1 April 2018 to 31 March 2019. We focus on some areas for improvement that we have seen through our work and include examples of actions that providers took in response to incidents. We expect providers to learn from these to help comply with the regulations and improve the quality and safety of care for patients.

We also report on the development of new guidance and other activity that involves CQC's IR(ME)R team.

We cannot compare the numbers of notifications received in this reporting period with those published in previous reports because of the different reporting periods (previously calendar year, now financial year). Some notifications may also have been re-classified to a different category following further investigation of previously open notifications.

NEW DEFINITIONS FOR RADIATION INCIDENTS

The enactment of IR(ME)R 2017 resulted in new and amended requirements for radiation incidents, affecting both healthcare providers and CQC. The wording and definitions relating to radiation incidents changed, with 'much greater than intended' (MGTI) replaced with 'significant accidental or unintended exposure' (SAUE).

CQC and the devolved administrations in the UK were tasked with reviewing the definitions of what constitutes a SAUE following the Department of Health and Social Care's consultation. In July 2018, we presented a case to our senior leadership team to seek approval to develop technical guidance for the new notification criteria to be used across the four nations. Guidance on this was published in June 2019.

Background to the new definitions

The Health and Safety Executive's guidance note 'Equipment used in connection with medical exposure' (PM77), was adopted as the original criteria for MGTI under IR(ME)R 2000. Although this was developed specifically for the Ionising Radiation Regulations 1999 (now revoked) for equipment faults, it was adopted in the interim for IR(ME)R 2000 while awaiting standalone criteria.

The criteria for notification were loosely based on the notifiable exposure having a radiation risk of one in 10,000. A multiplying factor was applied to the intended dose depending on the type of examination and intended dose for incidents. For example, for examinations with an intended dose less than 0.5mSv, a multiplication factor of 20 would have been applied.

Although this remained relevant for over-exposures (where a patient was intending to have an examination but received a higher dose than expected), it did not take into account exposures where none were required. This meant that when patients received a dose when none was intended, it would automatically trigger a notification to us as the multiplication factor would be infinite, even for low dose examinations. For example, a finger X-ray carried out on the wrong patient would always be notifiable, despite both the dose and risk being negligible.

The Department of Health and Social Care released guidance in January 2017 on the criteria for notification under MGTI. This was not intended to make dramatic changes because the new regulations would be released the following year. There was continued use of multiplication factors, with additional guidance to help interpret some areas, such as laterality errors in diagnostic imaging.

Where the MGTI 2017 guidance amended the definitions of what constituted a notifiable incident, there was a decrease in the numbers of notifications compared with previous years (by 28% between 2016 and 2017). Where guidance remained the same, the numbers were comparable with the previous years. Further information on these changes and their impact, are in last year's [IR\(ME\)R annual report](#). We were able to draw on our knowledge of investigating almost 8,000 notifications under MGTI, as well as more scientific evidence of risk, to develop the new [SAUE guidance](#), which we published on our website on 3 June 2019.

New criteria for notifications

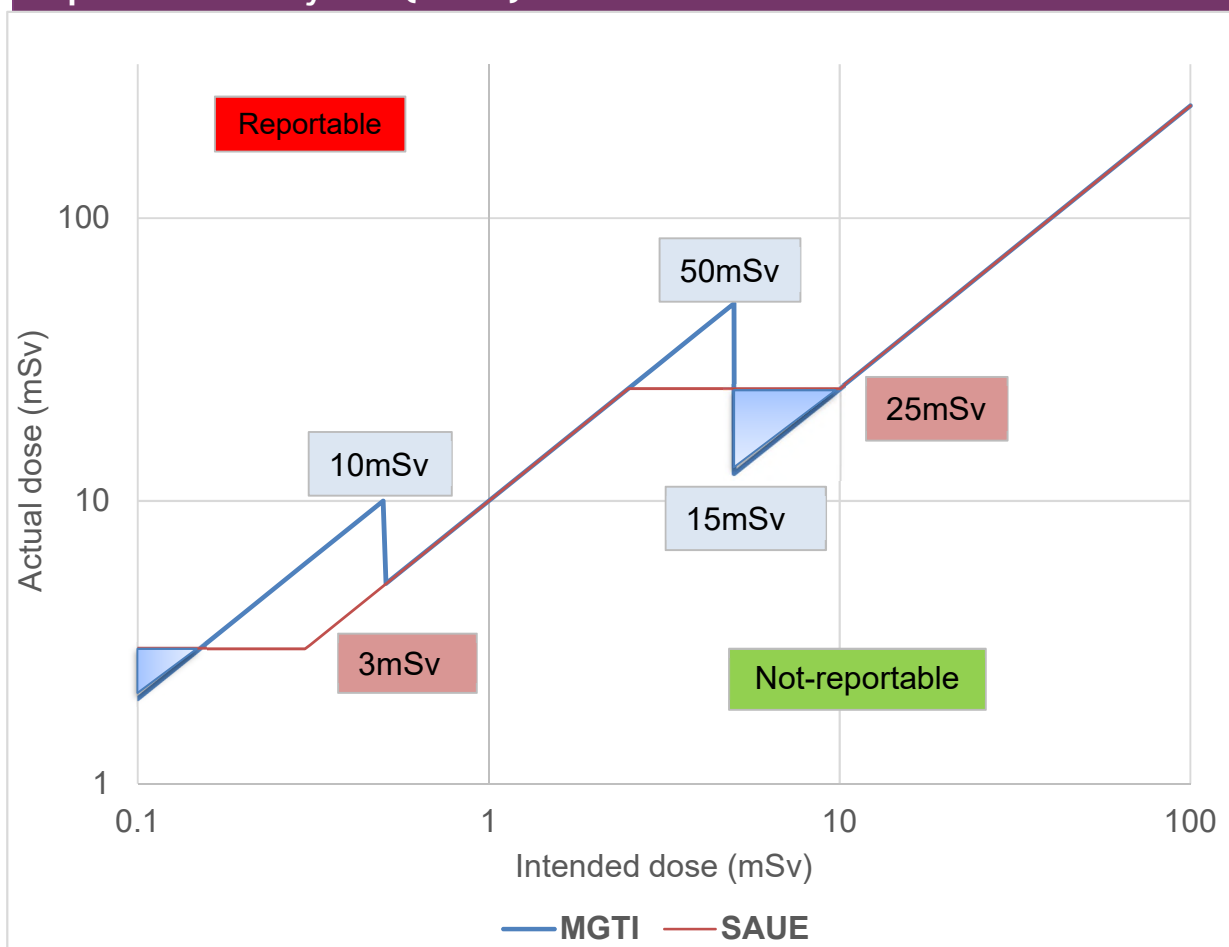
We based the new criteria on recommendations from the International Commission on Radiological Safety (ICRP)⁴ with the one in 10,000 risk model. This lifetime additional risk of cancer per examination has been classed as 'low risk'.

In England, we have also introduced thresholds for accidental or unintended exposures that are not notifiable. For adults, we have adopted 3mSv, based on the one in 10,000 risk model,⁵ which also closely aligns with the average yearly dose of exposure for people living in the UK.⁶ The other devolved administrations have chosen to retain all accidental exposures, regardless of dose.

The thresholds take into consideration the variation of radiation risk with a person's age at the time of exposure. As children are more radiosensitive, we have applied a factor of three to the thresholds for accidental and low dose unintended incidents involving children.

Figure 1 shows the differences between the old and new criteria based on the multiplication factors and dose thresholds. There are only two areas where previous notifications will no longer be notifiable (shown by the blue shaded triangles): the first relates to the lower threshold criteria of the 1 in 10,000 risk model explained above, and the second uses a fixed dose criteria for any accidental or unintended exposures, which will eliminate the previous inconsistency between the multiplication factors of 10 and 2.5x that were used under MGTI.

Figure 1: 'Much greater than intended' vs 'significant accidental or intended exposure' criteria by dose (in mSv)



Timeframes for making notifications

Regulation 8(4) defines the timeframe in which providers should notify us of an incident.

We have specified 12 weeks as the maximum period for submitting the detailed investigation as described in Regulation 8(4)(iv) (unless there are mitigating factors that were discussed with the inspector). This timeframe aligns with that specified in NHS England’s Serious Incident Framework.⁷ This regulation means that we now have the power to take enforcement action against providers who do not provide the required information soon enough.

Impact on the number of notifications

Based on data from the previous year, we predict a decrease in the number of notifications that we will receive under the new guidance. We expect the biggest impact to be on the number of diagnostic imaging notifications because of the low dose nature of these incidents, which will no longer reach the threshold criteria. For example, in 2018/19, we received 399 notifications where either the wrong patient had been referred or the operator failed to identify that they had exposed the wrong patient. Of these accidental exposures, 67% of adults received less than the 3mSv threshold and 84% of children received less than 1mSv (where both dose and age were given through the webform).

To anticipate the impact of the new guidance on the number of notifications we expect to receive, we compared the number of notifications received in the month of July 2018 with those received in July 2019. Although the new guidance had only been in place for a number of weeks at that time, and therefore not fully embedded, the number of notifications had already decreased by 50%, with a 66% decrease in diagnostic imaging notifications alone (figure 2).

Figure 2: Number of notifications received in July 2018 and July 2019

	July 2018	July 2019
Diagnostic imaging	60	20
Nuclear medicine	4	2
Radiotherapy	10	14
Total	74	36

New internal category codes

Alongside the new SAUE guidance, we have developed our new internal codes to categorise incidents. When we close a notification, inspectors identify the root cause and record it to enable us to collect data. Previous codes, such as the ones used in this report, were considered too simplistic and did not encompass the variety of errors we saw.

When we published guidance on SAUE in June 2019, we adopted new codes for diagnostic imaging and nuclear medicine errors, which align with the taxonomy established by the Clinical Imaging Board.⁸

In radiotherapy, we have aligned more closely to the well-established 'towards safer radiotherapy' taxonomy,⁹ and expanded our coding using experience from several years of investigating notifications.

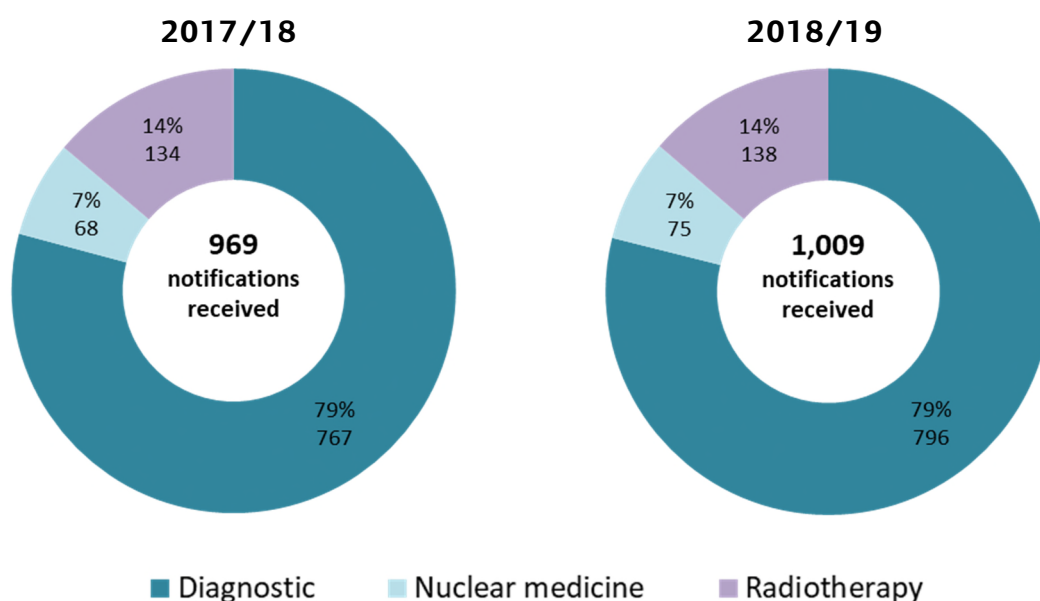
We have also updated our online notification form to reflect the new SAUE guidance, to enable us to understand the category under which providers are making the notification.

OVERVIEW OF ACTIVITY IN 2018/19

Notifications

During the year 1 April 2018 to 31 March 2019, we received 1,009 notifications across all modalities. This was comparable with the previous year where we received 969 between 1 April 2017 and 31 March 2018 (figure 3).

Figure 3: Total notifications received, 2017/18 and 2018/19



Activity data in England

NHS England's Diagnostic Imaging Dataset¹⁰ collects information about tests carried out on NHS patients. Over the past year, the use of diagnostic imaging and nuclear medicine has continued to grow. In 2018/19, 43 million diagnostic imaging examinations were carried out on NHS patients in England, of which almost 30 million¹¹ used ionising radiation.^a Activity across all imaging modalities grew by just under 2% compared with the previous year.¹²

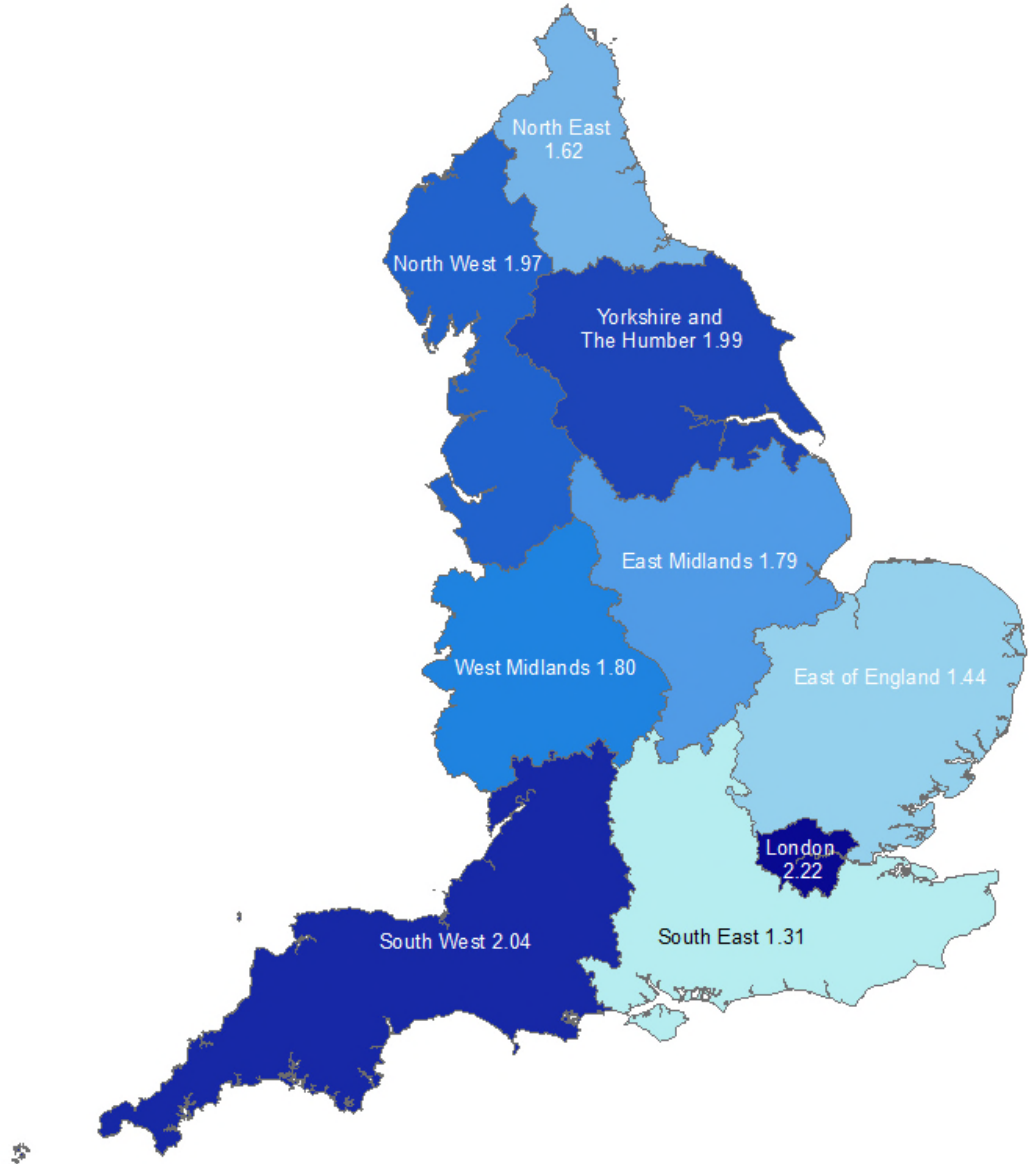
The National Cancer Registration and Analysis Service (NCRAS) produces data for the Radiotherapy Dataset (RTDS), which monitors all radiotherapy activity delivered in NHS hospitals in England.¹³ In 2017/18, there were over 133,000 episodes of radiotherapy treatment in England. This was a modest decrease from the previous year (0.7%).

a. 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, which shows a variation ranging from 1.31 in the South East to 2.22 in London (figure 4). We cannot be sure of the cause for the variation although it could include differing interpretations of the statutory notification guidance previously used, as well as the concentration of specialist trusts based in London. The introduction of the MGTI guidance in January 2017 may have improved consistency of interpretation (particularly around laterality errors) and notifications of incidents between major regional medical physics providers.

Figure 4: Number of notifications per 100,000 population, 2018/19



Inspections

As an enforcement authority, we carry out either planned inspections as part of a programme, or focused inspections in response to concerns or high-risk notifications. In this reporting period, we carried out 25 IR(ME)R inspections (figure 5).

Figure 5: Number of inspections per quarter, April 2016 to March 2019

	2016/17	2017/18	2018/19
Q1	5	5	4
Q2	4	5	8
Q3	1	5	7
Q4	5	2*	6
Total	15**	17	25

* IR(ME)R 2017 came into force on 6 February 2018

** Changing the category of 'visits' to 'inspections' means this figure is different to the 14 published in the 2017/18 report (which includes an extra quarter).

Of these 25 inspections, we carried out:

- 9 diagnostic imaging inspections as part of the planned paediatric radiology inspection programme
- 5 planned diagnostic imaging inspections (one of which was jointly with the Health and Safety Executive)
- 1 diagnostic imaging registration inspection
- 3 diagnostic imaging inspections in response to concerns
- 1 cardiology inspection in response to a notification
- 1 planned radiotherapy inspection
- 2 focused radiotherapy inspections in response to notifications
- 3 focused nuclear medicine inspections in response to notifications or concerns.

We anticipate carrying out more inspections during 2019/20, as the reduction in notifications will allow us to concentrate more on planned programmes and focused inspections.

Enforcement activity

In 2018/19, we issued Improvement Notices under IR(ME)R to eight NHS trusts through both our programme of planned inspections and focused visits. Some Improvement Notices covered a number of breaches of the regulations, while some cited only one.

Failures relating to employer's procedures resulted in enforcement action at six trusts. Five of these breaches were where trusts did not comply with Regulation 6(1)(a) by not having a full set of procedures in place as defined in schedule 2. We served a further three Notices for failures to make these available to staff or failing to maintain a programme of quality assurance for them.

We allowed an informal period of around six months to enable providers to revise and embed the new procedures required under IR(ME)R after the regulations were enacted in February 2018. However, even after this period we continued to find that a number of providers were still not complying with this regulation and had no plans in place to address the requirements.

We took enforcement action at four NHS trusts for failures to maintain a quality assurance (QA) programme of equipment and failures to perform testing at regular intervals. These failures occurred over a range of types of equipment, including a hybrid theatre and a gamma camera, but most commonly we saw gaps in testing records relating to plain film X-ray rooms and mobile image intensifiers.

Further details on the action we have taken are on our [enforcement register](#).

Key findings from inspections and notifications

The following are some key themes identified in 2018/19 that were common to all modalities. We expect that providers learn from them and improve their own compliance locally.

Governance frameworks

A common factor that contributes to poor compliance is an inadequate governance framework surrounding radiation protection.

Clinical governance is key to ensuring a clear chain of delegation that cascades accountability from the provider to the point of care, and ensures that information flows back to the responsible provider. However, it has been identified that hospital boards have not always received intelligence about some radiology services.¹⁴

Although we found the majority of providers had committees that reviewed all aspects of radiation, the links to more senior committees within the providers were sometimes unclear. Without these, we regularly found that tasks were poorly delegated from the IR(ME)R employer, and risks and assurances rarely fed back. This meant that risks identified in radiation protection compliance were not always sufficiently mitigated or controlled. It was particularly apparent for departments that were not run or staffed by radiation specialists, such as operating theatres.

We also found that large providers had issues with delegating tasks and sharing information downwards into departments. Some departments were establishing image optimisation teams, but we found little evidence of sub-committees or task groups that had the ability to carry out project work, audits and other tasks relating to radiation protection.

RECOMMENDATIONS

Review the scheme of delegation for tasks relating to radiation protection, for example ratifying procedures. This should include all services that use ionising radiation, particularly departments that do not have extensive understanding of the regulatory requirements, such as those outside of radiology departments.

Enable departments to feed into more senior committees. This helps to ensure that risks and assurances are shared and acted on.

Employer's procedures

As reported from our inspections of paediatric radiology departments, the content of the employer's procedures (as required under schedule 2) were not always adequate.

We commonly found these documents were composed of extracts from the regulations themselves unnecessarily, reading more like policy statements than actual procedures, and therefore did not give staff clear steps to follow to carry out tasks. This was most common where providers received standard templates from medical physics providers, which were designed to cover a range of different types of provider and services, and therefore did not always reflect local established practices.

RECOMMENDATIONS

Review the IR(ME)R employer's procedures to ensure they provide the appropriate information to enable staff to follow them. It is useful to have several separate procedures or standard operating procedures for different services. For example, staff working in nuclear medicine or interventional radiology departments have different practices around justification and consent to those of plain film departments.

Tailor the IR(ME)R employer's procedures to the intended clinical department and its specific work activities. Although there is a requirement to have all procedures in place, lengthy documents covering an entire provider do not always reflect local practice, so it is useful to have a shorter, more concise practical version for some areas and staff.

Incident management

The new SAUE guidance introduced timeframes for making notifications and submitting details of investigations.

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 21 (median) with a range of same day to 1,435 days. The new guidance specifies a maximum of two weeks after detecting the incident. This may require a change in local procedures to ensure they reflect the timescales set out in the SAUE guidance.

Some providers have not been redacting investigations, as required under data protection laws, when sending information to us. Again, we remind all providers that information submitted to us must not contain any details that could identify the patient, or the members of staff involved.

Example of action to improve compliance with local procedures

A large NHS trust introduced a new system of carrying out compliance audits in response to some incidents, and to support an application for Quality Standards for Imaging (QSI) accreditation (previously known as ISAS).

The audits were also part of a drive to maintain a supportive culture for staff in the imaging department. They were designed to ensure that radiographic staff comply with local procedures, for example in relation to use of 'Hello My Name Is', making ID enquiries, data management, IR(ME)R authorisation, patient property, manual handling, infection control and information given to patients following their attendance. A senior colleague audited a different sample of staff each month.

The resulting initiatives included developing a 'quality before speed' mission statement to support the established 'pause and check' recommended by the Society of Radiographers.

Although not in place for long, we heard that early feedback from staff in the department showed that the audit had been welcomed, supported good practice and is working well.

Example of action to improve the reporting culture

A professional head of radiology was completing a dissertation for their MSc. As part of this, they organised staff focus groups and produced questionnaires for staff with the aim of improving the reporting culture in the department. Using the findings, they delivered a workshop to over 60 members of staff, which covered a range of patient safety and incident reporting information, including:

- how to use online incident reporting systems
- what to report and when
- human factors
- the importance of raising concerns and reporting near misses.

Following the workshop, an audit found an increase in reporting rates, with the number of reported no-harm incidents or near misses rising by almost 80%. A further questionnaire also showed that communication had improved, and staff had a better awareness of patient safety and understanding of how incidents were investigated. Staff also reported feeling less blame was associated with reporting incidents and felt more encouraged to report.

A number of providers have improved the awareness of incidents through team meetings and displaying posters showing the number and types of incidents in conspicuous areas in their departments. Their staff have reported being more aware of incidents and a non-blame, open culture around errors.

Equipment

In this reporting period, we received 18 notifications relating to equipment failures, two of which were reported in error. Out of the 16 incidents, 15 occurred on diagnostic imaging equipment (six CT, one dental, eight plain film X-ray, one mobile X-ray), one involving a brachytherapy applicator, and one involving the cone beam CT on a radiotherapy linac. In six of these notifications, the age of the equipment was a contributing factor.

Although all the notifications involved radiation equipment directly, the SAUE guidance defines equipment to include ancillary equipment that would directly influence patients' doses. This would include contrast injectors, gamma cameras, and record and verify systems used in radiotherapy.

We have also found that many of the equipment inventories held by providers do not include the five specific fields as required by the regulations, with the year of manufacture (Regulation 15(2)(d)) commonly missed. Although in most cases the 'year of manufacture' is the same as 'year of installation', there is still a requirement to include both fields.

RECOMMENDATION

Check the age profiles and performance of equipment to reduce the risk of incidents. Regulation 15 sets out the duty to improve inadequate or defective performance of equipment. If it is not possible to replace ageing equipment, this should be flagged on a local risk register to manage it appropriately.

Foetal exposures

Between 1 April 2018 and 31 March 2019, we received 25 notifications of foetal exposures across all modalities.

Only one of these involved a procedural failure. In this case, even by following the procedure, the operator would not have been able to identify the pregnancy, as the procedure was poorly written and required practitioner involvement, which was not standard clinical practice in the department. Following the investigation, the procedure was amended to reflect the established practice carried out by the operators within the department.

The remaining 24 notifications all related to undeclared or unknown pregnancies, where operators followed their local employer's procedures. Investigations found that either patients were unaware of their pregnancies as they were very early, and they had denied any possibility, or the pregnancy testing was not accurate. Six of the notifications were from radiotherapy departments and all of these involved at least one fraction of treatment while pregnant. None of these cases were a result of procedural failure and, despite well-established practices at all points of the patient's pathway, pregnancy was not identified.

Example of foetal exposure error and action taken

An unintended foetal exposure happened after standard checks had failed to detect a pregnancy of five months gestation, despite standard enquiries at consent, pre-treatment imaging and on day one of treatment. As traditional methods failed to detect the pregnancy, rather than changing the operator's practice, the provider's actions focused on the communication with patients. This included:

- updating the wording on the consent form to include an explanation of the consequences of becoming pregnant during treatment
- updating the checklist to determine whether the patient had already received a clear explanation of how therapies can adversely affect pregnancy.

These changes were made in conjunction with chemotherapy 'at-home' processes.

DIAGNOSTIC IMAGING

Notifications in 2018/19

We received 796 diagnostic imaging notifications in 2018/19. This was a 4% increase compared with the same period in the previous year. Diagnostic imaging comprised 79% of all notifications received in both 2017/18 and 2018/19. Of all diagnostic imaging notifications, 94% were from NHS acute trusts.

The diagnostic sub-modality with the highest proportion of notifications was computed tomography (CT) (figure 6).

This follows the trend seen from 2013 to January 2017, when the majority of all diagnostic imaging notifications involved CT (56-60%). After guidance from the Department of Health and Social Care was published in January 2017, the proportion of CT and plain film X-ray notifications became more aligned.

Despite plain film X-ray examinations accounting for 53% of all activity in the diagnostic imaging department^b, CT comprises the highest proportion of notifications received. This is because of the differing criteria in the statutory notification guidance. Notifications received in the other diagnostic imaging sub-modalities have largely remained comparable with previous years, except for mammography, which had increased by over 50%.

Figure 6: Diagnostic imaging notifications received by sub-modality, 2017/18 and 2018/19

Sub-modality	2017/18		2018/19	
	Number of notifications	% of total	Number of notifications	% of total
CT	356	46%	370	47%
Plain film X-rays	361	47%	361	45%
Mammography	18	2%	28	4%
Dental	10	1%	16	2%
General fluoroscopy	11	1%	13	2%
DEXA	5	1%	4	1%
Interventional radiology	4	1%	3	0%
Cardiac	2	0%	1	0%
Total	767	100%	796	100%

b. Including X-ray, CT, ultrasound, MRI and fluoroscopy.

Effective doses

The number of doses received in error for plain film X-ray notifications reduced from 2017/18 to 2018/19 (figure 7). Based on the average doses for plain film X-ray notifications, we expect to receive far fewer from this modality following the new SAUE thresholds, as few notifications involve doses to patients over 3mSv.

Figure 7: Average accidental or unintended dose received in error (mSv), 2017/18 and 2018/19

Sub-modality	2017/18	2018/19
CT	9.6	8.2
Plain film X-rays	1.1	0.5

It is important to note that this is not based on all notifications received because of issues with how incident dose is recorded in notification forms – for example, not all doses are given in mSv, some are expressed as a range or as text such as “various”.

It is unclear whether the doses that providers stated on our webform are just the unintended/accidental element, or the total dose received. When completing online notifications, we ask providers to ensure that the effective dose stated is solely that which has been given in error. We have recently amended wording to make this clearer.

Types of error

After we review a provider’s investigations, we internally categorise incidents based on the root cause they have identified. We then group these categories into the type of duty holder (referrer or operator) to which the incident originates and the type of error that occurred.

Figure 8 on the next page shows that the most common type of error is still when the wrong patient receives an exposure, with 50% of all diagnostic imaging errors resulting from referrers failing to refer the right patient and operators failing to actively identify their patients.

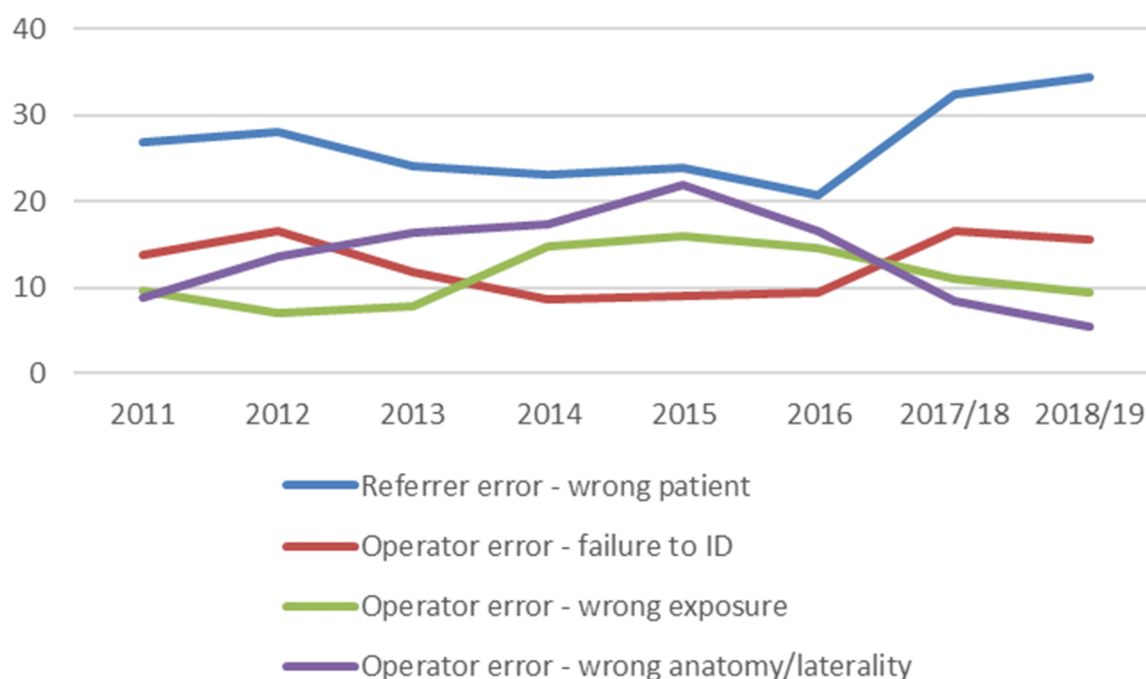
Figure 9 shows that this has consistently been the case for the previous eight years. Although ‘pause and check’ has raised awareness of the importance of making checks with the patient and associated documentation, the initiative in itself cannot completely eliminate all such errors.

Figure 8: Diagnostic imaging notifications received by detailed error type, 2017/18 and 2018/19

Detailed type of error	2017/18		2018/19	
	Number of notifications	% of total	Number of notifications	% of total
Referrer error – wrong patient	249	32%	275	35%
Operator error – failure to ID patient	127	17%	124	16%
Operator error – wrong exposure set	84	11%	75	9%
Operator error – wrong anatomy / laterality	65	8%	44	6%
Operator error – modality selection	44	6%	36	5%
Timing error / NGT timing	39	5%	37	5%
Operator error – no check of previous imaging	35	5%	47	6%
Referrer error – no check of previous imaging	33	4%	41	5%
Referrer error – wrong anatomy / modality	31	4%	31	4%
Operator error – other	22	3%	21	3%
Volunteered (or not meeting criteria)	16	2%	12	2%
Operator error – image archive / labelling	12	2%	7	1%
Equipment failure	5	1%	15	2%
Inadequate supervision	3	0%	9	1%
Other	2	0%	22	3%
Total	767	100%	796	100%

Note: Foetal exposures are categorised as ‘other’ and equipment failures were only reportable from February 2018.

Figure 9: Type of error as a percentage of total, January 2011 to March 2019



The number of wrong anatomy or laterality errors has reduced significantly since 2016. This was not related to improvements in clinical practice; rather, we believe the reduction was due almost entirely to the change of definitions in the MGTI guidance, meaning the majority of incidents did not meet criteria for notification.

RECOMMENDATION

Consider carrying out a more detailed investigation of the circumstances for repeated types of error. A review of working practices could include:

- environmental factors such as distractions, poor design, or lack of available equipment
- task factors such as the appropriateness of procedures, understanding or complacency of staff
- human factors, such as working automatically without proper attention, or ineffective communication
- staffing factors such as ineffective leadership, fatigue or overload, or inappropriate skill mix.

Example of improving engagement with pause and check

A provider had seen a number of incidents where operators had failed to formally identify patients or make final checks of exposure factors. In response, they used a new approach to ensure that staff were more engaged with the 'pause and check' initiative. As well as writing a reflective statement, the approach required staff to fill in a blank copy of the 'pause and check' poster after an incident.

Example of action to limit distractions

A provider identified that distraction was a factor in a number of incident investigations. Its actions to address this included:

- the radiographer scanning in CT wearing a tabard, as nurses do when dispensing drugs, which signals they must not be distracted during scanning
- removing telephones in the reviewing areas (apart from one for emergencies) and moving to an area where calls can be taken without distraction
- limiting the CT viewing area to essential staff only.

Inspections

We carried out 15 planned inspections of diagnostic imaging departments in 2018/19 and a further five in response to concerns received from various sources.

A notification from a cardiology department was made voluntarily as it did not meet the criteria, but we still inspected the department to gain a better understanding of the context of the incident. The notification related to a cardiologist who was neither entitled nor had associated training records to operate the equipment without a radiographer being present. Our inspection found that the incident had been well investigated and actions had been implemented. Compliance within the department was also good.

We carried out two inspections following concerns around incident management – one where investigations were not carried out quickly enough, and the other where the quality of the reports was inadequate. Our second inspection resulted in enforcement action in relation to schedule 2, as the provider did not have a full set of procedures in place or the governance framework to address this.

Key themes from diagnostic imaging inspections and notifications

The following are some key themes identified from our work in diagnostic imaging, along with recommendations and examples, which providers can learn from and improve their own compliance locally.

Plain film X-ray equipment

Through our work in both notifications and inspections, we identified a theme in relation to the optimisation of protocols and programmes on plain film X-ray equipment.

Between 1 April 2018 and 31 March 2019, we received 12 notifications of incidents involving children aged two or under, where exposure factors had defaulted to adult factors.

Investigations found the main cause of the incident to be a failure by the operator to 'pause and check'. However, many found the set-up of the equipment to be a contributing factor.

Examples included:

- defaulting back to adult settings after a five-minute gap for preparation
- when performing a new exposure (repeat or second view) defaulting to the top thumbnail, which was an adult protocol
- mapping between RIS code and equipment protocols not performed and automatically defaulting to adult factors.

We also found failures with mapping of programmes in other areas. This included a provider whose equipment was rarely used, particularly for this type of examination. The equipment was not mapped to the RIS code, nor the protocol reviewed. Therefore, when the radiographer selected the examination, it defaulted to the basic device factors. In this case the radiographer failed to 'pause and check' and did not observe that an oblique wrist was given 70kV/40mAs, which is far more than the required factors.

In 2018/19, we received 57 notifications where the operator had used the wrong exposure factors during a plain film X-ray examination. Again, 'pause and check' failures were the root cause, but the set-up of the equipment was not always appropriate. The large turnover of patients in an X-ray department and the increase in the use of digital systems means radiographers are becoming very reliant on the equipment settings, and the automated nature of processes means they are not always performing the required checks. The majority of notifications relate to the incorrect selection of the bucky, AEC or detector.

Example of diagnostic imaging error

During an inspection, we observed radiographers in a newly-installed diagnostic radiology room, which had been in use for a few months. Although the radiographers were highly experienced and were able to demonstrate knowledge of the local protocols, we found the defaults from the manufacturers were still in place in the room, which did not reflect the exposure charts or even the protocols used in the identical adjacent room.

Although the radiographers were comfortable in amending the factors to those required for all patients, this disconnection leaves the opportunity for error.

Mammography

We have continued to see two common themes in notifications relating to breast imaging:

- failures to check the patient's age before determining the imaging modality
- patients receiving both symptomatic and screening mammograms within a six-month period, contrary to guidance.¹⁵

Although the first theme could be resolved with better administration processes and educating staff about the age groups, the latter theme is more difficult to control. Established practice in many providers relies almost entirely on the patient remembering the date of their last mammogram. This means when a patient cannot remember or does not understand the examination itself, checks have failed, resulting in repeat mammograms.

An interim report for a commissioned review on national cancer screening programmes in England identified inefficiencies from using multiple IT platforms to obtain patient information.¹⁶ The report states that many of the systems in use are outdated and interoperability can be poor. NHS Digital manages the system used to call and recall women for breast screening, and a private provider hosts the system used to record the outcome of appointments. By introducing other local systems outside of the national programme, the opportunity to review previous imaging is difficult, and we regularly see this as a contributory factor in notifications of repeat mammograms.

NUCLEAR MEDICINE

Notifications in 2018/19

We received 75 notifications from nuclear medicine in 2018/19, which was an increase of 10% over the previous year. These comprised 7% of the total number of notifications received, with 83% from NHS acute trusts.

The numbers of nuclear medicine notifications have been broadly consistent over recent years (figure 10). This is also the case when broken down by type of error (figure 11).

Of the 75 notifications, 62 originated from 40 individual NHS trusts, with the remaining notifications originating from five independent healthcare providers. The maximum number of notifications received over the year from a single provider was four.

Figure 10: Nuclear medicine notifications received by sub-modality, 2017/18 and 2018/19

Sub-modality	2017/18		2018/19	
	Number of notifications	% of total	Number of notifications	% of total
Diagnostic	62	91%	71	95%
Therapeutic	6	9%	4	5%
Total	68	100%	75	100%

Figure 11: Nuclear medicine notifications received by type of error, 2017/18 and 2018/19

Type of error	2017/18		2018/19	
	Number of notifications	% of total	Number of notifications	% of total
Operator / admin error	35	51%	33	44%
Referrer-patient-ID	26	38%	30	40%
Foetal exposure	4	6%	6	8%
Other	3	4%	6	8%
Total	68	100%	75	100%

Key themes from nuclear medicine inspections and notifications

We carried out two focused inspections in nuclear medicine. A further inspection carried out in April 2018 was part of a study investigating reported breaches in the new licensing of radioactive substances required under IR(ME)R 2017.

Therapy

Of the four notifications from nuclear medicine therapy, two related to foetal exposure where the patient reported after treatment that they had been pregnant at the time, despite previously declaring they were not pregnant. There had been no breakdown in the pregnancy procedure with these notifications.

Another notification related to the wrong clinical protocol and activity being selected for thyroid ablation according to its staging, which was not considered significant clinically. Following this, the therapy request form and work instruction were modified to include checking of previous treatments.

The remaining notification described an extravasation incident during a patient's Lutetium-177 Dotatate therapy, where there were no obvious signs during the administration. It was identified that the patient had unstable venous access. In response, staff training and procedures were strengthened to reflect best practice.

Diagnostic

Notifications from diagnostic nuclear medicine comprised patient identification errors, failure to cancel examinations that were no longer required, and administrations of the incorrect radioactive medicinal product (RMP). This was comparable with notifications in 2017/18 and previous years.

Those notifications labelled 'Other' related to breaches in Administration of Radioactive Substances Advisory Committee (ARSAC) licensing and equipment faults.

We have received a number of notifications where the incorrect tracer was administered in PET-CT, for example, FDG instead of choline.

RECOMMENDATION

Before administering nuclear medicine, a multi-point check should include a check against the original request to ensure the correct scan has been selected.

All IR(ME)R duty holders need to be vigilant, follow procedure and adopt safe practice at all stages of the nuclear medicine pathway.

Administration of Radioactive Substances Advisory (ARSAC) licensing

A new requirement of IR(ME)R 2017 is for employer and practitioner licences for the use of radiopharmaceuticals. These are replacing the certificates from the now withdrawn Medicines (Administration of Radioactive Substances) Regulations 1978 (MARS), under transitional arrangements.

Under Regulation 5 of IR(ME)R 2017, all exposures involving the administration of radioactive substances must be covered by a licence that describes whether the administration is for diagnosis, treatment, or research. Licences are issued by ARSAC and processed by Public Health England on behalf of the 'Licensing Authority', which in England is the Secretary of State for Health and Social Care.

Under these new arrangements, practitioner licences are no longer site-specific and instead all radioactive substance administrations at a location must be included in an employer 'site' licence. Transitional arrangements also allow practitioner certificates granted before 6 February 2018 to serve as a site licence for as long as the certificate remains valid. More information on the transitional arrangements and new applications is in the ARSAC guidance from Public Health England.¹⁷

Breaches in compliance with licences

We became aware of five separate nuclear medicine providers that had administered radioactive substances without the appropriate practitioner certificate or licence during 2018. These were across both NHS and independent healthcare providers.

For most, the provider volunteered the breach information, in one case by a notification. We heard about one breach indirectly, where the provider initially reported the difficulty to the ARSAC Public Health England secretariat.

Three breaches related to sentinel lymph node (SLN) procedures, where doses were low and a small number of patients were involved.

To understand the timing and nature of the breaches, we visited each provider to see how the non-compliance was being addressed, and to determine whether incidents were temporary and isolated or whether they represented a wider problem.

The main outcomes from this initial programme of work are:

- Before IR(ME)R 2017, the process for obtaining ARSAC certificates was well established. Applications were relatively simple and often managed personally by the practitioner. We do not have data on ARSAC certificate breaches under MARS although at least one occurrence was the subject of an IR(ME)R MGTI notification. When details of the transitional arrangements were first discussed, we were made aware of two of the breaches to MARS just before the enactment of IR(ME)R 2017.
- The need for employer site licences was a significant new challenge, particularly for larger departments with specialist nuclear medicine provision. These applications require more detailed information than the previous certificates, for example details of staffing, entitled

practitioners, service, radiopharmaceutical and medical physics expert provision, governance, equipment and a detailed list of diagnostic, sealed/unsealed therapy, and research procedures to be licensed.

- Three breaches related to confusion on 'functional' grouping of vulval/oral SLN and lacrimal drainage procedures, which meant they were not included in some applications. Elsewhere, communication difficulties within the department meant that PET-CT scanning was performed for a few days before the new employer's site licence was approved.
- We have received only one report of a breach since early 2019, and licence provision checks as part of relevant SAUE notifications show a more satisfactory compliance. We believe this is due to continued bedding-in of the new licensing agreements and familiarity with the ARSAC guidance and application arrangements.
- Between 1 April 2018 and 31 March 2019, 716 licence applications were made under IR(ME)R 2017.¹⁸ Application forms and guidance were updated in response to feedback from nuclear medicine departments.
- Under a memorandum of understanding with Public Health England, we engage regularly with the ARSAC support unit, sharing intelligence and discussing key topics, such as the variation in level of support from medical physics experts to nuclear medicine providers.

RECOMMENDATION

Involve a multidisciplinary team when applying for site licences for radioactive substance administrations. Management checks and ongoing audit are essential to ensure the licence covers all existing clinical practice and to accommodate any relevant departmental changes and service developments. A written procedure, including the line of accountability to the employer, helps staff and management.

Expert advice

Regulation 12 of IR(ME)R 2017 defines the nature and level of expert advice needed, including for nuclear medicine practices. When reviewing notifications, and in our licensing programme, we found a wide variation in levels of involvement by medical physics experts, particularly for diagnostic practices. We have escalated our concerns where we believe the level of involvement is not sufficient to meet the requirements of Regulation 12. We will review this in more detail in 2019/20.

Nuclear medicine equipment

The age and performance of SPECT CT or other cameras has featured in several IR(ME)R notifications. As well as Regulation 15, we draw attention to Regulation 15(6), where the employer must specify acceptable performance criteria of equipment and take any measures necessary to improve inadequate or defective performance.

Example of equipment error and action taken

A provider depended on ageing SPECT CT cameras at two sites and notified us when both experienced intermittent faults resulting in relatively low risk under SAUE criteria. The department adopted advice from the manufacturer and engineering and physics experts, and agreed an acceptable performance criterion. They introduced more QA checks and carried out more frequent preventative 'warm-ups'.

While waiting for a business case and subsequent approval for a replacement camera, the provider maintained a risk-assessed, adequate service for patients. The IR(ME)R notification was kept open with regular monthly updates, so that we were informed on current status, risks and outcomes.

RADIOTHERAPY

Notifications in 2018/19

We received 138 radiotherapy notifications in 2018/19, representing 14% of all notifications received (figure 12). Of these, 91% were received from NHS acute trusts.

There was a small increase in the number of radiotherapy imaging notifications (including pre-treatment and verification imaging), but a decrease in treatment notifications compared with the previous year (figure 13).

Figure 12: Radiotherapy notifications received by sub-modality, 2017/18 and 2018/19

Sub-modality	2017/18		2018/19	
	Number of notifications	% of total	Number of notifications	% of total
Planning/verification imaging	51	38%	60	43%
Beam therapy (radical)	43	32%	48	36%
Beam therapy (palliative)	34	25%	27	20%
Brachytherapy (radical)	6	4%	2	1%
Brachytherapy (palliative)	0	0%	1	1%
Total	134	100%	138	100%

Figure 13: Radiotherapy notifications received by type of error, 2017/18 and 2018/19

Type of error	2017/18		2018/19	
	Number of notifications	% of total	Number of notifications	% of total
Radiotherapy imaging	51	38%	60	43%
Treatment error	59	44%	47	34%
Planning error	9	7%	16	12%
Referral error	8	6%	8	6%
Other	7	5%	7	5%
Total	134	100%	138	100%

Public Health England's Medical Exposures Group publishes a regular analysis of data for radiotherapy errors and near misses provided voluntarily by NHS providers in the UK. The type and severity of incident are categorised using a coding taxonomy described in Towards Safer Radiotherapy.¹⁹ Analysis of this data shows that around 1% of incidents reported through this voluntary collection are notifiable to the relevant inspectorate. This remains in line with the previous year.²⁰

Key themes from radiotherapy notifications

We identified that a noisy and disruptive environment was just one factor in many of the notifications received from radiotherapy departments. We describe other key themes, and examples of responses to incidents, to help providers to comply with IR(ME)R and better patient safety.

Pre-treatment imaging/referral errors

We received 29 notifications of errors in pre-treatment imaging and referrals in 2018/19. The causes included:

- referring for radiotherapy before all the required diagnostic information was in place to support the referral (in one case based on erroneous histopathology results)
- failure to communicate changes to patient management
- not checking for previous radiotherapy
- referring for the wrong site or wrong dose/fractionation.

Some notifications involved radiographers working in pre-treatment imaging who had either selected the wrong scan protocol or anatomical range. In one case the radiographer scanned the patient before they had seen a clinical oncologist (that is, without a referral/justification).

Example of pre-treatment error and action taken

This notification involved an incident where more anatomy than necessary was scanned for prostate CT planning. The referring doctor intended to treat only the prostate and seminal vesicles of a patient, but the referral was for prostate and pelvic lymph nodes treatment.

This was because the doctor wanted to refer the patient for a high treatment dose (74Gy in 37 fractions), which was only available by referring under the 'prostate and pelvic lymph nodes' protocol on the trust's electronic radiotherapy referral system.

The trust's investigation found this had happened previously with five other patients.

The older 74Gy option had been removed from the e-referral system for prostate + SV, although this higher dose option was still permitted under a clinical protocol for 'prostate + pelvic lymph nodes'.

The new prostate protocol intended for prostate +SV was 60Gy/20# (arising from CHHiP). The additional dose arose entirely from the additional volume scanned.

The incident was discussed at oncology and radiotherapy clinical governance meetings to raise awareness, and the trust's investigation report made the following recommendations:

- Reinstatement of the protocol 'Prostate + SV 74/66Gy in 37#'.
- Set up an annual audit to check that all radiotherapy prescriptions currently included in clinical protocols on the quality management system match those available for consultants to select from the e-requesting system.
- Include a new table in all clinical protocols ensuring that all necessary staff in the radiotherapy department have read the protocol and signed to indicate they are aware of any changes.

Example of pre-treatment error and action taken

In this notification, the oncologist assumed that a patient had spinal metastasis as they had a history of pain and recent history of spinal metastasis elsewhere, so referred them for CT planning scans before they had received the formal radiologist report.

Two consultant clinical oncologists (CCOs) had discussed the case, agreed the diagnosis and made a referral for planning CT scans. However, a radiologist reported two days after this, and determined the cause was degenerative spine rather than metastasis. As soon as the CCO saw the report, they emailed to cancel the planning scans, but they had already been completed. The patient did not proceed to treatment.

The trust learned several lessons and made changes to avoid a repeat:

- The clinical oncologist reflected on this incident and in future will not refer for radiotherapy without a confirmed diagnosis and a formal report.
- The incident was shared with the radiographer and wider oncologist teams for awareness. It was also discussed at Radiotherapy Multi Professional and Radiation Safety meetings, the trust's quarterly Radiation Safety Committee, and the oncology clinical governance meeting.
- The clinical governance meeting determined that, except in exceptional emergency circumstances and only where determined by a CCO to be in the patient's clinical best interests, no radiation exposure should be given without a confirmed radiological or histological diagnosis and that only a CCO can make these referrals.
- A procedure was agreed for cases when a patient needs emergency treatment and a delay in preparing that treatment while waiting for a written radiologist report could have a significant adverse clinical outcome. In these circumstances, the clinical oncologist must contact the reporting radiologist to ask for an urgent verbal report while waiting for the formal written report.

Treatment errors

We received 47 notifications of treatment errors in 2018/19, the majority of which were in relation to geographical misses. Of these, 31 were partial misses and only one was a total miss.

Public Health England provides some useful information in its Safer Radiotherapy report issue 28, with a case study arising from a vertebral image mis-match.²¹

Example of treatment error and action taken

A patient receiving treatment for breast cancer received a single field from a plan intended for another patient.

The patient was identified through electronic documentation stored in the patient management system, but when another patient with a similar name was loaded onto the treatment console, verification checks between the two systems were not conducted according to departmental procedures.

The mistaken field was for the same clinical site and approximately the same dose. The first field of the wrong plan was delivered before the error was noticed and treatment was then paused.

Statements from staff involved in the incident mentioned that there had been an IT issue immediately before the error, and there was a subsequent rush to catch up with patient treatments.

In response to the incident, the employer's procedures were reviewed and updated. In the revised procedure, operators working in treatment areas were required to make checks using a photograph of the patient to identify them, which operators could see on computer monitors in treatment rooms.

Staff were reminded of the new procedures, which were to be audited to help identify potential sources of distraction to further improve compliance in a paperless environment.

The department also planned to hold focus groups to find out what pressures the treatment staff face, and how to alleviate them.

Example of treatment error and action taken

This notification was for a patient with lung cancer who was receiving palliative treatment. Following an online mis-match of an area, the patient received a partial geographical miss for a single fraction.

Following the incident, clinical protocols were reviewed and a new protocol developed, which recommended kV pair imaging for palliative chests with arms up. The protocol also included specific structures to be matched for palliative chest treatment, specifically T1 and first rib onto the DRR to aid the match.

Staff were informed of the changes to protocol and received training on the new image matching process, and a new monthly audit of palliative thorax imaging was arranged.

The provider's investigation also looked at the pressures on treatment radiographers who carry out image matching, to enable them to make changes to improve the working environment.

Planning, checking and data entry

In this reporting year, we received 16 notifications that we attributed to an error in clinical mark-up, planning, plan checking or data entry.

Example of planning error and action taken

We were notified of a planning error where a male patient received a single fraction of 10Gy to an area of pelvic nodes that was not intended to receive it. The patient was meant to have two pelvic lymph nodes treated, however the registrar wrongly contoured a third node, remote from the intended two, which was approved by their consultant who prescribed 30Gy/3# to 2 GTVs.

The patient was set up and imaged and the third nodal volume was spotted during image verification. After discussions, the planner acknowledged that three nodal volumes had been marked up and the planning dose assessment sheet had been signed. The decision was made to continue to treat the patient. After the first fraction was delivered, the consultant was contacted and confirmed only two nodes were to be treated.

The provider's investigation report comprised a comprehensive action plan:

- Protocols were amended to require each volume to be contoured individually with clearer, more consistent labelling, for example GTV1, and GTV2. The location now needs to be recorded on the treatment sheet against the associated GTV number.
- A box was added to the plan assessment form to require the planner/checker to review the number of lesions against what is written on treatment sheet.
- Staff were encouraged to speak up and seek advice if they found any inconsistencies, and consultants were asked to be more vigilant when checking marked up plans

Verification imaging

We received 39 notifications of errors in verification imaging (out of 60 in the radiotherapy imaging category). Most were 'selection errors' of the wrong protocol (often a body protocol when a head protocol was intended), resulting in an over-exposure well above the 2.5x criteria as notifiable by SAUE guidance. Other notifications included incorrect scheduling of the imaging, with misunderstanding of whether a weekly or daily protocol was required. Only a small number of these were notifiable when there were five or more imaging events over the course of treatment.

Example of verification imaging error and action taken

This error involved protocol selection over two fractions. The patient required daily cone beam CT imaging using a brain/paediatric protocol but received 68 times the intended dose when a pelvis protocol was selected in error. At the next fraction, there was a partial scan using pelvis mode before the radiographers realised the error and terminated the exposure.

After an audit, the trust identified a further 19 patients who had received over-exposures arising from incorrect selection of imaging protocol, nearly half of which would have met notification criteria. The majority of these involved the selection of a body protocol when brain had been intended.

The trust investigated the causes and contributory factors and identified several actions:

- Moving a patient between treatment machines was found to reset the CBCT scan parameters. A subsequent software update allowed for 'persistent parameters' in such circumstances, although the trust also noted this only worked if the protocol name was exactly the same on each linac.
- Investigation showed that it is easy to inadvertently change the CBCT protocol by scrolling with the mouse wheel after selection. The local policy describing the checks before exposure has been amended to specify that the final check of the CBCT protocol must be carried out after selecting 'OK', when unintentional amendment is no longer possible.
- The order of scanning protocols on the drop-down menu were described as confusing. The protocols were in order of those most frequently used, which sometimes resulted in some of the highest radiation dose protocols being next to the lowest. In response, the trust amended the order of the CBCT protocols in the drop-down list, with the low dose protocols at the top and high dose modes at the bottom.
- There was no clear policy for which CBCT protocol was associated with what treatment area, or what active checks should be made, and no awareness of the difference in dose between protocols, as this was not clearly documented. Documentation on CBCT scan was scheduled to be updated after the incident.
- The environment was found to be noisy and disruptive, causing distractions to staff. A 'task and finish' group was set up to review possible changes.

Findings from radiotherapy inspections

In 2018/19, we carried out three inspections of radiotherapy departments. This included our first planned inspection in March 2019 as part of a new programme of radiotherapy departments, which is set to continue for the foreseeable future. Our last programme of inspections of radiotherapy departments was 10 years ago, with a [thematic report](#) published in 2011.

Some findings from inspections mirrored those seen in other modalities, such as schedule 2 procedures not reflecting local practice.

However, we found that some providers had carried out a considerable amount of work around the regulatory requirement to develop a QA programme to include a 'study of the risk' of exposures judged to be 'significant accidental and unintended'. Despite risk assessments being established practice in all radiotherapy departments, not all have a distinct 'study of risk' document to comply with Regulation 8(2).

Two inspections were in response to concerns. One was in response to a notification where a patient received a repeat orthovoltage treatment of the same area, which had been treated several months earlier. The patient, requiring treatment of another area, received an inadvertent repeat prescription as their full notes were not available at the time the action sheet was filled in, and there were significant distractions for the practitioner at the time of request. Subsequent lack of checks at mark-up and along the pathway allowed the error to translate into the full course of 10 fractions of 4.5Gy each. A variety of contributory factors had led to the error, including:

- IT difficulties and delays in scanning notes
- personal circumstances of the practitioner
- lack of orthovoltage work instructions/formal check list
- the orthovoltage service not being part of the established procedures and practice embedded in other external beam therapy departments in the trust.

In response to the incident, the provider developed new orthovoltage procedures and a checklist, strengthened radiotherapy 'script' and extended appointment slots for planning/treatment. Our inspection also acknowledged that this was a time of change for the service, with wider developments in staffing and support that would enable orthovoltage to benefit from becoming more integrated within the rest of the radiotherapy department.

CQC's WIDER IR(ME)R ACTIVITY IN 2018/19

Paediatric radiology inspection programme

In July 2019, we published the findings of a 24-month planned inspection programme of paediatric radiology services. We carried out 12 inspections of NHS providers of specialist children's services in England. During this programme, we issued three Improvement Notices (under the Health and Safety at Work Act 1974) for lack of up-to-date or incomplete employer's procedures, as required under Regulation 6(1)(a). We served a further three Improvement Notices for failing to maintain a quality assurance programme of equipment.

[Our report](#) summarises our findings and includes recommendations to help all types of providers to improve compliance with IR(ME)R across all radiology services.

Enforcement policy

We established an internal working party in September 2018, to conduct a full review of our IR(ME)R enforcement policy and supporting documentation.

In February 2018, we published an interim policy, to reflect the change in some powers around equipment under IR(ME)R 2017. After the new regulations were implemented, we reviewed the policy further to include our new powers to investigate equipment faults and non-medical imaging providers, and to ensure that IR(ME)R inspectors follow a consistent and proportional approach to enforcement.

Following a short consultation with professional bodies, we published CQC's new [IR\(ME\)R enforcement policy](#) in June 2019.

IAEA integrated regulatory review service UK mission

The Minister for Energy and Business 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.

This took place in October 2019 and included all UK bodies involved in regulating the use of ionising radiation across all sectors, including nuclear energy, industrial radiography, and medical exposures. The review compared the UK regulatory infrastructure with the IAEA Basic Safety Standards²² and used a range of methods, including self-assessment, interviews with representatives from organisations and observing inspections. A report will be published in due course.

Committee on medical aspects of radiation in the environment

The Committee on Medical Aspects of Radiation in the Environment (COMARE) is an expert advisory committee of the Department of Health and Social Care, providing independent advice to the government on the health effects from radiation. The Department asked COMARE to review the evidence on the practice of using DXA scans for sports performance assessments and other non-medical practices within the UK.

In July 2019, COMARE released its 19th report on the issues for sports performance assessments using DXA scans, which concluded that more evidence is needed for use of DXA for body composition analysis when used outside a recognised training programme.²³ We will discuss the next steps with our legal and policy teams, as well as the Department of Health and Social Care, to ensure there is appropriate regulation of the use of DXA. This is pending the decision from the Justification of Practices Involving Ionising Radiation Regulations 2004 (JoPIIR) about whether the use of DXA outside of health screening and medical use is justified.

Supporting CQC's inspections in radiology and dental providers

CQC's team of IR(ME)R inspectors has continued to support inspections of hospital and dental providers under the Health and Social Care Act 2008. This has involved policy and enforcement work to support the programme of inspections of single specialty providers of diagnostic imaging. We have also updated the [core service inspection framework](#) for diagnostic imaging inspections of both NHS and independent acute providers to include the most up-to-date guidance from the professional bodies and the changes required by IR(ME)R 2017.

As well as this, we have also worked with colleagues in the Primary Medical Services directorate to review the methodology for dental inspections. We have supported the training of general inspectors and developed numerous online training packages for colleagues covering a range of imaging modalities.

NEXT STEPS

We have started our programme of planned inspections, including interventional radiology and nuclear medicine departments, and continue with the inspections of radiotherapy departments.

We will be concentrating on key topics, including:

- under Regulation 14, the provision of medical physics experts and their involvement
- under Regulation 8(3), incident management where incidents do not meet SAUE criteria.

We will look at the findings of our peer review from the IAEA mission, and take the appropriate actions to ensure we improve our processes. This will likely include a scoping exercise to detect and gather intelligence about providers of non-medical imaging and chiropractors.

We are discussing with the professions how to improve the information we provide to the radiology and radiotherapy communities in relation to investigations into errors. Much of next year's report will concentrate on the impact of the new SAUE guidance, but we will also be able to provide more detailed information and findings from carrying out more inspection activity. We aim to test a new approach to providing additional information to professions arising from SAUE and other clinically significant events in radiotherapy.

As the number of notifications decreases, we will also be reviewing methods to enable us to gather more intelligence about providers and their compliance with the regulations.

APPENDIX: 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, with 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.

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