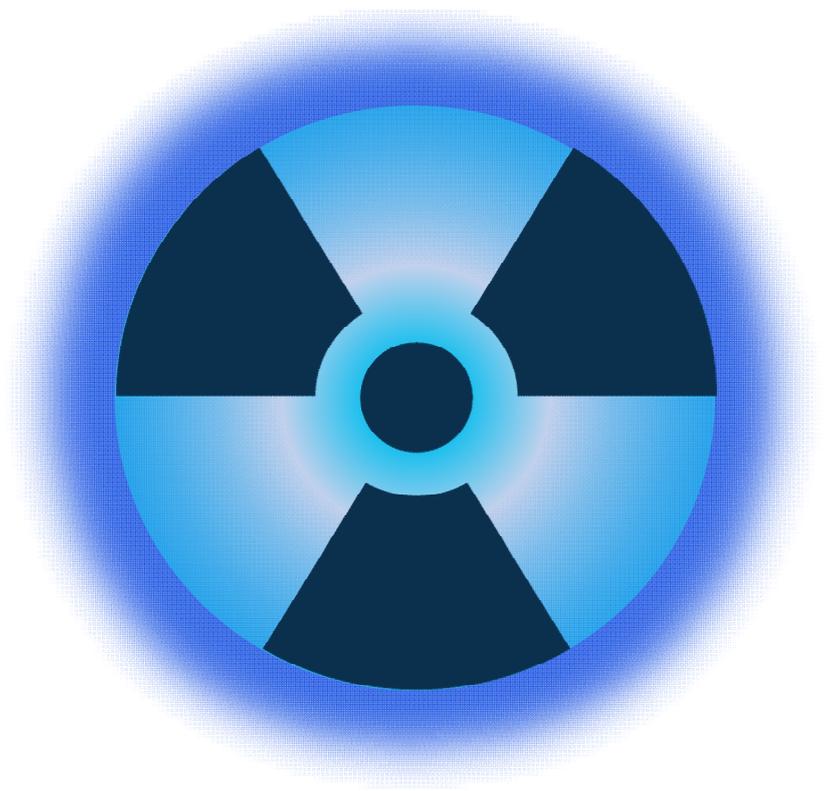


IR(ME)R annual report 2021/22

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

November 2022



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KEY POINTS

Notifications received in 2021/22

From 1 April 2021 to 31 March 2022, we received 611 statutory notifications of significant accidental and unintended exposures (SAUE notifications) across all modalities. This compares with 499 received in 2020/21, an increase of 22%.

- 366 (60%) were from diagnostic imaging departments
- 63 (10%) were from nuclear medicine departments
- 182 (30%) were from radiotherapy departments.

Diagnostic imaging notifications: The most common type of error is still where a patient received an examination meant for another patient (27% of all diagnostic imaging notifications), although this has decreased from 36% in 2020/21. We received 75 notifications where the wrong patient had been referred for diagnostic imaging examinations.

In a change from last year, operator errors accounted for the highest origin of incidents reported to us (40%), rather than referrer errors. We received 24 notifications where the operator failed to correctly identify a patient.

The highest proportion of notifications from diagnostic imaging (63%) was from CT (computed tomography).

Nuclear medicine notifications: Errors were most often reported from PET-CT and PET-MR. Operator errors are still the major source of notifications. Mistakes in the preparation or administration of radiopharmaceuticals was the most common of these.

We also continue to see a large number of notifications relating to the performance of equipment.

Radiotherapy notifications: There has been a marked increase in the number of notifications in radiotherapy from the previous year. This was almost entirely in planning and verification imaging, which increased from 69 to 110 notifications. This was due to an increase in the use of short course fractionation regimes, for example five fraction breast treatments.

Inspections

In 2021/22, we inspected:

- 14 diagnostic imaging departments
- 6 nuclear medicine services
- 13 radiotherapy departments.

Key trends and concerns

- As in previous years, a key source of errors continued to be when the wrong patient received an examination that was meant for another patient. Inadequate checks about the patient's identity by both the referring clinician and the operator were common causes of errors.
- There was a need to ensure that procedures, protocols and guidance for staff are up-to-date and effective, and to improve processes when investigating incidents.
- Many of our regulatory recommendations involved the need to improve the quality and availability of training records for staff.
- Some recommendations involved making the best use of the valuable input from medical physics experts. We also made recommendations to employers to improve how they monitor the risks posed by the shortage of medical physics experts.

Themed inspection programmes

Neurointerventional imaging

This inspection programme was developed specifically for the neurointerventional services of the 24 specialist NHS centres. Common themes included:

- Risks from ageing equipment – equipment over 10 years old is no longer state-of-the-art and it is important to replace it to benefit from latest new software and dose saving technologies, which offer significantly lower doses and enable exposures to be optimised effectively.
- Employer's procedures – some were too generic as they covered several services within a trust and did not always reflect the specific practice carried out in the department.
- Referral guidelines – these were not always being implemented or made available to referrers, and need to include radiation doses for referrers.
- Patient doses – all services we visited had adopted dose levels for a range of examinations, and most had set diagnostic reference levels (DRLs) for interventional radiology procedures.

Mobile CT services

We have trialled a programme of inspections on mobile CT services. During the COVID-19 pandemic there was an increase in the number of mobile CT units in the independent sector. Notifications highlighted risks to patients unique to this type of service.

- Complying with written procedures – some parts of the patient pathway were shared with other employers, which meant the provider needed to rely on others to ensure duty holders were appropriately entitled and trained.
- Standardising protocols – the rotation of staff between different host sites sometimes meant radiographers needed to use a variety of examination protocols for different types of examinations. This meant that several patients needed to be re-scanned using the correct protocol. But contractual agreements offer limited ability for a mobile CT service to standardise protocols between host sites.
- Co-operation between host sites – reviewing and managing incidents was disjointed, resulting in delays in concluding investigations and findings not shared between employers. This also led to duplicated statutory notifications and delays in submitting reports of notifications.
- Limited clinical audits – the mobile nature of the service meant there were few clinical audits embedded within the governance programme, with another employer carrying out much of the clinical evaluation and justification.

Chiropractic services

Our inspections of services run by chiropractors registered with the General Chiropractic Council (GCC) aimed to increase our understanding of compliance standards within chiropractic using radiography. Although subject to professional regulation from the General Chiropractic Council, chiropractors are exempt from registering with CQC under the Health and Social Care Act 2008. However, IR(ME)R still applies.

Early feedback from the first 3 inspections showed poor compliance with and understanding of IR(ME)R requirements:

- Medical physics experts – we believe it is crucial for chiropractors to work closely with their medical physics experts and to adopt diagnostic reference levels.
- Employer's procedures – these were generally incomplete and not maintained or regularly reviewed.
- Referral guidelines – these were either unavailable or there were several different sets.
- Quality assuring equipment – arrangements varied from not happening at all to a visual inspection only, or a medical physics expert QA testing equipment once every 3 years.
- Training records – there were no records of practical or equipment training for chiropractors who took X-rays.

We are keen to continue our pilot chiropractic inspection programme as we remain concerned about poor compliance and understanding of IR(ME)R requirements among this profession.

INTRODUCTION

The Ionising Radiation (Medical Exposure) Regulations 2017 are known as IR(ME)R. They provide a regulatory framework to protect people against the dangers from being exposed to ionising radiation in a healthcare setting. The regulations state that each individual exposure should be justified and optimised to make it as effective as possible, and to ensure that the benefit for the patient outweighs the risk.

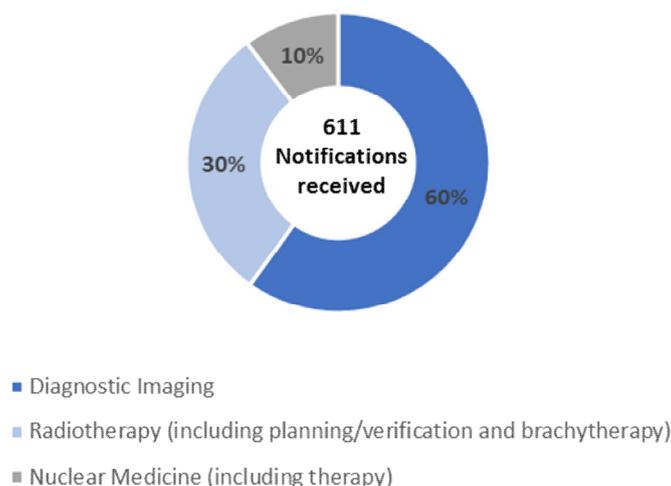
We enforce the regulations in England through on-site inspections and by reviewing statutory notifications from healthcare services about significant accidental or unintended exposures to patients. In this report, we provide an update on what we found from notifications received in the period 1 April 2021 to 31 March 2022, and from our inspection and enforcement activity over this period.

We also highlight some key concerns around compliance with the regulations and provide examples of actions from IR(ME)R employers to improve the quality and safety of care, so that other employers, healthcare professionals and academic bodies can learn from them.

Notifications received in 2021/22

- From 1 April 2021 to 31 March 2022, we received 611 statutory notifications of significant accidental and unintended exposures (SAUE notifications) across all modalities. This compares with 499 received in 2020/21, an increase of 22%.
- The largest proportion of notifications came from diagnostic imaging (60%).

Figure 1: Notifications received by modality, 1 April 2021 to 31 March 2022



Source: CQC notifications data 2021/22

Activity data in England

NHS England collects information about tests carried out on NHS patients in England in the [Diagnostic Imaging Dataset](#). [Data for 2021/22](#) shows that between April 2021 and March 2022, NHS services in England carried out 43.8 million imaging tests across all modalities. Of these examinations, 29.9 million used ionising radiation (including plain film X-rays, CT, fluoroscopy, nuclear medicine, PET-CT and SPECT, as opposed to other types of test such as ultrasound, MRI scans or medical photography).

The Radiotherapy Dataset (RTDS) is managed by the National Cancer Registration and Analysis Service (NCRAS). It collects, curates and analyses data on all radiotherapy activity delivered in NHS hospitals in England. In 2021/22, there were over 134,000 episodes of radiotherapy treatment in England, an increase of 8% on the previous year. This is likely due to the ongoing recovery of services following the COVID-19 pandemic. **Note:** the completeness of radiotherapy activity data varies by trust and trusts may submit historical data at a later date. Therefore, it is possible that some data may still be missing and that there may be changes to overall figures as the RTDS is updated over time.

Notifications from diagnostic imaging

- 366 notifications received (329 notifications received in 2020/21)
- represents 60% of all notifications received
- 89% of notifications were from NHS acute trusts
- the highest proportion of notifications from diagnostic imaging (63%) was from CT (computed tomography)

Figure 2: Notifications from diagnostic imaging received by sub-modality, 1 April 2021 to 31 March 2022

Sub-modality	Number of notifications	% of notifications
CT	229	63%
Plain film X-ray	72	20%
Interventional radiology/cardiology	24	7%
Mammography	15	4%
General fluoroscopy	10	3%
Dental (including CBCT)	7	2%
Theatre/mobile fluoroscopy	5	1%
DXA	4	1%
Total	366	100%

Types of error

The most common type of error has continued to be where a patient received an examination meant for another patient (27% of all diagnostic imaging notifications), although this has decreased from 36% in 2020/21. We received 75 notifications where the wrong patient had been referred for diagnostic imaging examinations, and 24 where the operator failed to correctly identify a patient. Figure 3 shows the number of detailed errors where tier 1 is the causative factor, with tiers 2 and 3 the contributory factors.

In a change from last year, operator errors accounted for the highest origin of incidents reported to us (40%), rather than referrer errors. We have seen a marked increase in the number of incidents attributed to pre-exposure checks (77 up from 38 last year).

Figure 3: Notifications from diagnostic imaging by detailed error type, 1 April 2020 to 31 March 2021

Tier 1		Tier 2		Tier 3	
Employer	2	Employer's responsibility	2	Inadequate procedures	2
Referrer	112	Incorrect referral	78	Wrong patient	75
				Wrong timing	2
				Wrong anatomy	1
		Incorrect information	34	Failure to cancel	21
				Duplicate/no check of previous imaging	8
				Inaccurate clinical information	5
Practitioner	4	Justification	1	Incorrect justification	1
		Protocol	3	Illegible/unclear protocol	3
Operator	145	Pre-exposure checks	77	Wrong patient position/setup/protocol	44
				Wrong use of equipment	33
		Patient checks	28	Patient ID error	24
				Failure to check pregnancy/breastfeeding	4
		Clinical history	16	Failure to check history/details	16
		Post examination	13	Failure to upload images	12
				Reporting failure	1
		Authorisation	10	Incorrect authorisation	10
Pharmaceutical/contrast	1	Administration	1		
Equipment	58	Equipment related	58	Hardware	30
				Software	18
				IT failure	8
				Ancillary failure	2
Other	45	DRL/Deterministic	15	Deterministic effects	10
				10x DRL	5
		Patient related	10	Unknown pregnancy	9

			Patient issue	1
	Made in error or withdrawn	7	Duplicate notification/other error	7
	Other	6	Not listed above	6
	Administrative staff error	5	RIS input error	3
			Other admin error	2
	Test results	2	Request based on incorrect results	2
Total	366	366		366

Examples of initiatives to address increases in errors

Re-energising the PAUSED poster

As radiology services returned to normal working following a COVID spike, the radiology and physics department in one employer became aware of an increasing proportion of referrer errors for the wrong patient. These were mostly detected within radiology as 'near misses'.

There was a sense within the department that the existing PAUSED posters to remind staff about pause and check had become 'invisible' to colleagues who were meant to be aware of them.

The employer involved their own communications department to launch a campaign called 'Getting it Right'. This was to re-energise the awareness of both referring clinicians and colleagues in radiology about the importance of checking. As part of this, they updated the existing PAUSED poster and produced a new poster that embraced the principles of the existing work, while focusing on 8 key essentials in one poster aimed at both groups of staff.

The posters were launched alongside what was initially called a 'perfect IR(ME)R week' with the support from the trust's Medical Director who provided a YouTube video message to all staff to support the message. The trust also used this new poster as a screen saver for referrers using the trust's IT systems.

Dedicated PAUSED posters for head CT

Two doctors at another employer carried out a clinical audit that looked at requests for CT head scans against NICE guidelines. The evidence from the audit suggested that some patients received scans that may not have met guidelines, and some patients did not get a CT scan as there was not enough clinical information on the requests.

In response, the employer created a checklist for referrers similar to the PAUSED checks developed by the Society of Radiographers. These were tailored to the service specifically for CT head scans using criteria from NICE.

Notifications from nuclear medicine

- 63 notifications received (35 notifications in 2020/21)
- represents 10% of all notifications received
- 68% of notifications were from NHS acute trusts
- 38% of notifications were from PET-CT and PET-MR

There has been a marked increase in the number of nuclear medicine notifications since 2020/21. This has been across all 4 sub-modalities and cannot be attributed to any one field.

These figures do not include any notifications relating to licensing breaches, where a SAUE did not occur. We manage these voluntary notifications through a separate process and [webform](#).

Figure 4: Notifications from nuclear medicine by sub-modality, 1 April 2021 to 31 March 2022

Sub-modality	Number of notifications	% of notifications
PET-CT/PET-MR	24	38%
Diagnostic imaging	22	35%
Radionuclide therapy	13	21%
In vitro study	4	6%
Total	63	100%

Source: CQC SAUE notifications 2021/22

Types of error

Operator errors are still the major source of notifications. Mistakes in the preparation or administration of radiopharmaceuticals was the most common of these (figure 5).

We also continue to see a large number of notifications relating to the performance of equipment. In 2021/22, we received 3 notifications of equipment issues caused by failure of ancillary systems, in contrast to the previous year when there were none. These tended to relate to failure of chillers and cooling systems in imaging suites, which caused the scanner to stall.

Figure 5 Notifications from nuclear medicine by detailed error type, 1 April 2021 to 31 March 2022

Tier 1		Tier 2		Tier 3	
Referrer	13	Incorrect referral	9	Wrong patient	7
				Wrong anatomy	1
				Wrong modality	1
		Incorrect information	4	Failure to cancel	4
Practitioner	1	Safety checks	1	Patient ID error	1
Operator	24	Pharmaceutical/contrast	13	Preparation	8
				Administration	5
		Pre-exposure checks	6	Wrong use of equipment	5
				Wrong patient position / set-up / protocol	1
		Authorisation	2	Incorrect authorisation	2
		Clinical history	1	Failure to check history/details	1
		Patient checks	1	Patient ID error	1
Post examination	1	Failure to upload images	1		
Equipment	11	Equipment related	11	Hardware	7
				Ancillary failure	3
				Software	1
Other	14	Administrative staff error	4	Other admin error	3
				RIS input error	1
		Patient related	4	Patient issue	3
				Unknown pregnancy	1
		Other	4	Not listed above	4
Made in error or withdrawn	2	Below threshold	2		
Total	63		63		63

Source: CQC SAUE notifications

Licensing notifications

Employers can notify us voluntarily about licensing breaches using a separate webform outside of the process for statutory notification of SAUEs. We have received only a small number of notifications in this area, but key themes included:

- practitioners failing to renew their licence, which the employer did not detect
- research studies going ahead before the employer’s licence was in place
- certain procedures accidentally omitted from the application form when applying for a new or renewed licence.

We investigate each licensing breach to look for any trends that we can highlight to help employers. Any further action we may take depends on the risk involved.

Notifications from radiotherapy

- 182 notifications received (135 notifications received in 2020/21)
- represents 30% of all notifications received
- 96% of notifications were from NHS acute trusts
- planning and verification imaging accounted for 60% of all radiotherapy notifications received

Data from the [National Cancer Registration and Analysis Service relating to the Radiotherapy Dataset](#) showed there were over 134,000 episodes of radiotherapy treatment in England between April 2021 and March 2022, an increase of 8% on the previous year. **Note:** the completeness of radiotherapy activity data varies by trust, and trusts may submit historical data at a later date. Therefore, it is possible that some data may still be missing and that there may be changes to overall figures as the RTDS is updated over time.

Figure 6: Notifications from radiotherapy by sub-modality, 1 April 2021 to 31 March 2022

Sub-modality	Number of notifications	% of notifications
Planning and verification imaging	110	60%
External beam therapy	67	37%
Brachytherapy	5	3%
Total	182	100%

Types of error

There has been a marked increase in the number of notifications in radiotherapy from the previous year. This was almost entirely in planning and verification imaging, which increased from 69 to 110 notifications. This was due to an increase in the use of short course fractionation regimes, for example five fraction breast treatments. When carrying out these regimes, if any additional image is taken because of equipment or procedural failure, it triggers the notification threshold.

Figure 7: Notifications from radiotherapy by detailed error type, 1 April 2021 to 31 March 2022

Tier 1		Tier 2		Tier 3	
Referrer	21	Incorrect referral	17	Not in accordance with guidelines	9
				Referral premature	4
				Wrong treatment protocol/dose/fractionation	4
		Incorrect information	4	Failure to cancel	3
				Failure to check relevant history	1
Practitioner	9	Justification	9	Target volume/outlining error	5
				Wrong plan or protocol authorised	3
				Failure to cancel	1
Operator	84	Treatment	61	Verification protocol error	20
				Geographical miss – shift error	11
				Geographical miss – verification image online	11
				Incorrect immobilisation	9
				Geographical miss – no verification image	5
				Geographical miss – verification image offline	2
				Skin app treatment	2
				Total body irradiation/total skin electron therapy	1
				Planning	13
		Inappropriate plan generated	3		

		Pre-treatment	10	Wrong scan protocol selected	5
				Patient positioning error	3
				Immobilisation/marketing error	2
Equipment	58	Equipment related	58	Hardware	37
				Software	18
				Ancillary failure	2
				IT failure	1
Other	10	Made in error or withdrawn	5	Below threshold	5
		Patient related	3	Unknown pregnancy	2
				Patient issue	1
		Administrative staff error	1	Other admin error	1
		Other	1	Not listed above	1
Total	182		182		182

Inspections and enforcement activity in 2021/22

Using a graded approach to regulatory activity

In response to findings from the International Atomic Energy Agency's peer review in 2019, we have reviewed our approach to scheduling inspections. Along with the IR(ME)R enforcement authorities in Wales, Northern Ireland and Scotland, we take a [graded approach to our work](#).

This means that the levels of analysis, frequency of inspection and actions we are required to take are proportionate to the extent of the radiological hazards posed by the modality or practice. This means that we focus more resources on those areas that pose a greater potential radiological risk to patients, such as radiotherapy and nuclear medicine therapies, and less on those such as dental and plain film X-ray.

Diagnostic imaging

During the year, we carried out:

- 14 inspections
- 2 dental inspections

In some cases, our inspections involved multiple visits to assess compliance at different locations operating under one employer, or to investigate compliance following enforcement action. We found 21 cases of non-compliance with the regulations in diagnostic imaging and made 47 recommendations following inspection activity. Most recommendations are similar to those from previous years. We discuss some examples in more detail under the key themes in diagnostic imaging.

Regulations 6(1), 6(2) and 6(5)(b): As in previous years, the most common recommendations related to the employer's procedures. We made 14 recommendations to ensure that employers have a full set of procedures that clearly set out their intended purpose of supporting staff when delivering care, and that reflect clinical practice.

Regulation 8: 8 recommendations related to incident management, where we asked employers to improve processes for investigating incidents, monitoring themes and making statutory notifications to CQC as the enforcing authority.

Regulation 15: We cited equipment in 9 recommendations, 5 of which related to the need for audit trails to include information on quality assurance records, faults and associated actions. A further 4 recommendations related to updating equipment inventories to ensure they include all mandatory fields.

Other recommendations related to establishing diagnostic reference levels and monitoring the risks posed by a shortage of medical physics experts.

As a result of our work, we also issued 7 Improvement Notices. See further information on these in our [enforcement register](#).

Alongside our usual IR(ME)R compliance inspections we worked with colleagues under the Health and Social Care Act and supported 2 inspections.

Nuclear medicine

During the year, we carried out 6 inspections and made 19 recommendations as a result, relating to:

- **Regulation 6(1):** required written procedures, particularly those set out in Schedule 2 (4 recommendations)
- **Regulation 6(5)(c):** the frequency of review of dose data to inform diagnostic reference levels (1 recommendation)
- **Regulation 7:** insufficient clinical audit arrangements (2 recommendations)
- **Regulation 8:** arrangements for unintended or accidental exposures, including the study of risk for radiotherapeutic exposures (3 recommendations)
- **Regulation 12:** shortfalls around optimisation, including the exposures of carers and comforters (3 recommendations)
- **Regulation 15:** quality assurance of equipment and the content of the equipment inventory (3 recommendations)
- **Regulation 17:** arrangements for training and keeping training records (3 recommendations)

There was no enforcement activity in nuclear medicine during 2021/22.

Radiotherapy

During the year, we carried out:

- 13 inspections
- 3 additional compliance visits to follow up

From these inspections, we issued 7 Improvement Notices and made 22 recommendations. These included:

- **Regulations 6 and 6(1):** reviewing the employer's procedures to ensure they reflect clinical practice, with an appropriate quality assurance process (5 recommendations)
- **Regulations 17, 17(2) and 17(4):** training records for duty holders, with particular focus on practitioners (6 recommendations).

Other recommendations related to arrangements for clinical audit, accidental or unintended exposures, involvement of the medical physics expert and the performance of equipment.

One Improvement Notice followed an inspection under the Health and Social Care Act, where we noted non-compliance relating to quality assurance of protocols and procedures.

Key themes and concerns in 2021/22

Key themes in diagnostic imaging

Through our work in diagnostic imaging over 2021/22, we have identified some significant concerns and themes in specific areas. We've taken the learning from these to provide some actions that employers can take to help encourage improvement in these areas.

Registering novel or high-dose diagnostic services

When a new provider applies to register with CQC to carry on a regulated activity, our Registration teams assess the application and supporting evidence to make sure the provider will be able to meet regulations.

We assisted with assessing 4 registration applications from providers that were all intending to provide novel or high-dose diagnostic services. The assessments involved 2 site visits.

Two of the applicants were independent providers intending to deliver services in patients' own homes using a domiciliary X-ray machine. Our reviews found poor quality documentation, including both IR(ME)R-related and other documents that we need to see to be assured about safety, such as safeguarding and infection control policies. Although contracted medical physics experts had provided templates to the service, the employer had not adapted them to the service. For example, one service referenced CT scanners in its employer's procedures even though it was not using them, and the other service included inappropriate examinations in its protocols such as whole spine X-rays.

It was clear in our interviews with both these employers that they were unaware of the significance of these documents and had not received appropriate advice from the contracted medical physics service.

Dental inspections

Our team of dental inspectors carries out inspections of primary care dental services (10% of all dental services registered with CQC). This includes the arrangements for dental radiography. Our IR(ME)R team has rarely carried out inspection visits of individual dental radiography services as there is a lower level of risk associated with the low doses to patients.

However, in 2021/22 we carried out 2 dental inspections as part of a sampling exercise to assess compliance with IR(ME)R and a further 2 in the first quarter of 2022/23. We inspected 2 traditional dental services led by dental surgeons registered with the

General Dental Council and 2 imaging services providing cone beam CT, orthopantomogram and cephalometry X-rays, carried out by radiographers and trained/qualified dental nurses.

What we found

- Each service had a contract with a medical physics expert to support with all relevant aspects of the regulations.
- The majority of Schedule 2 employer's procedures were in place, although we found these did not always reflect local practice.
- Programmes of quality assurance for local equipment were not always carried out in line with established professional guidance, with some only comprising visual checks, with no further exposure checks.
- There were only minimal records of training, although the records we did see were generally good.

Key themes in nuclear medicine

Through our work in nuclear medicine over 2021/22, we have identified some concerns and themes in specific areas. We've taken the learning from these to provide some actions that employers can take to help encourage improvement in these areas.

Factors affecting therapy administrations

We received 13 notifications relating to radionuclide therapies. In 12 of these, the patient received a dose that was more than 10% higher or 10% lower than that prescribed for them (for example, over 110% or under 90% of the prescribed dose). A number of root causes contributed to these:

- 5 involved high residual activity or incorrect set-up of administration equipment, such as different tubing sets, leaking connections or air bubbles in the line.
- 4 notifications related to delivery issues for iodine-131, due either to supply interruptions or incorrect reference dates.
- 1 related to a SIRT (selective internal radiation therapy) administration where an occluded hepatic artery led to a blocked catheter that had to be discarded.
- 1 case involved an extravasation of radium-223.
- In another case, 2 operators failed to notice that the activity of an I-131 capsule was 11% higher than intended.



Actions for employers

- Make sure you have the correct equipment available for administering radionuclide therapies. Where you need to use different tubing, consider testing levels of residual activity in them before clinical use.
- When ordering therapeutic radiopharmaceuticals, make sure you use the latest advice from the manufacturer on lead times.
- Operators must check the reference date, time and activity of delivered radiopharmaceuticals carefully. You should check that this is embedded in their processes and that more than one operator makes these checks.

Gas used for ventilation during lung scans

An incident was reported where multiple patients received sub-optimal lung ventilation-perfusion (VQ) scans. Usually, the process uses argon gas as a carrier to suspend and transport technetium-99m particles to the patient's lungs. However, a cylinder that was used to supply the Technegas generator contained an air-like gas composition rather than argon. This had a negative impact on the image quality and increased background counts.

In this instance, hospital porters were responsible for delivering new canisters when needed. They had inadvertently replaced the argon cylinder with another containing an air-like gas, and this mistake was not detected by departmental staff for a week. During this time, six patients had undergone VQ scans.

When the error was detected, the department asked for advice from pharmacy and anaesthesia colleagues, as well as the manufacturers of the gas and generator. All agreed that there would be no detriment to the patients' health. A radiologist reviewed all six scans and identified two that needed to be repeated. The portering management team were notified and a new process was implemented where a member of staff checked the gas cylinder at delivery and the scanning operator made a check before administering Technegas. This was reinforced through updating procedures, sharing learning with all relevant members of staff and updating competency checks for operators.

Actions for employers

- Consider implementing checks of gas cylinders before starting VQ scans, to ensure operators are using the correct gas.

Activity scaling for paediatric studies

We received an enquiry from an employer concerning scaling activities for paediatric administration of radiopharmaceuticals, based on the values set out in the Administration of Radioactive Substances Advisory Committee's [ARSAC Notes for Guidance](#). This gives fractions of adult administered activity based on approximately 2kg intervals, which means that activities for children whose weight falls between these values is open to some interpretation. Some departments use interpolation to calculate an activity fraction based on the individual child's weight; others round up the child's weight to the nearest value instead.

Actions for employers

- Agree an appropriate method for scaling paediatric activities with the practitioner(s) and state this in departmental procedures. Use ongoing audit activities to ensure that staff adhere to this chosen method.

Key themes in radiotherapy

Through our work in radiotherapy over 2021/22, we have identified some concerns and themes in specific areas. We've taken the learning from these to provide some actions that employers can take to help encourage improvement in these areas.

Authorising additional imaging

To ensure the optimal treatment for patients, there is a need for additional imaging – either pre-treatment scans or on-treatment verification. All exposures, including concomitant doses that arise when using imaging to guide the treatment itself, need to be authorised by practitioners. However, in practice this is not always achievable, and the task is often delegated to operators in accordance with protocols defined by the practitioner. These protocols usually have a defined number of additional images that can be taken before involving a clinician and can only be approved by specific individuals, for example a pre-treatment superintendent radiographer or an imaging specialist.

During inspections we found poor training and associated records relating to who can authorise additional imaging. Often, the ability to authorise further images is linked to a job role or band, for example superintendent radiographer or any Band 7 radiographer. However, there is no specific training or competency that demonstrates that the individual can perform that task initially or how that competency is maintained. We did see some examples of good practice, which include defined competencies and enhanced IR(ME)R training for individuals who are authorising additional imaging, but this is the exception.

Actions for employers

- Document the process to authorise additional imaging and ensure that the training for any person entitled to do this is properly trained through a clear associated training package.

Commissioning new equipment

Commissioning new equipment, specifically new linacs (linear accelerators) or superficial treatment machines, is a complicated process so this is not a routine event. As such, it is unlikely that centres will have defined procedures or processes for installing and commissioning equipment and therefore will take more of a project management approach. As part of this process, the delivered dose of ionising radiation to the patient must be measured and assessed, not just the output of the machine.

Example: Incorrectly calculating the dose output on a new machine

We received a notification relating to the installation of a superficial treatment machine. An error in calculating applicator factors resulted in multiple patients receiving an average underdose of 21% over an 11-month period. A member of staff who was calibrating a new chamber holder for the equipment noticed the error as they were checking a new version of the planning dataset. They spotted a difference that they couldn't explain and raised it with the medical physics experts, who conducted 3 independent calculations and concluded that the original planning dataset was incorrectly calculated.

The centre suspended treatments and carried out dose assessments for all affected patients, who were contacted according to the employer's duty of candour policy.

The error resulted from a failure to update a spreadsheet that was used to calculate the planning dataset, which reflected the change in the length of the applicator. This meant the new machine gave a lower dose rate. The second person checking this new planning dataset did not go back to first principles and used the same dataset, which meant that the error was not noticed.

As the output measurements from the machine were correct, the initial commissioning process and subsequent daily quality assurance checks also did not raise any concerns.

During the 11-month period when patients were being incorrectly treated, the treatment radiographers noted that the times to deliver standard doses were different to the original machine. Although the treatment radiographers raised this with the medical physics team, their response was that longer times were to be expected based on the physical differences of the machine (having longer applicators) and the measured dose rates. In this case, incorrectly calculating the dose output meant that patients were incorrectly treated.

Most centres do not carry out patient-specific quality assurance of treatment as most systems are not capable of performing in-vivo measurements on a kV beam without degrading the treatment. This makes it even more vital to assess the dose of ionising radiation to the patient during commissioning – not just the output of the machine.

Actions for employers

- Make sure the commissioning process for new equipment is adequately documented and covers the entire end-to-end process. The process to assess the dose delivered to the patient for all treatment modalities must also be documented, even ones that are not easily assessed.

Clinically significant accidental or unintended exposure

Regulation 8(1) requires that when there is a clinically significant accidental or unintended exposure (CSAUE), the employer's procedures referenced in schedule 2 must set out the process for:

- informing the referrer, practitioner and individual involved
- providing information on the outcome of the investigation of the incident.
- reporting the incident if it is deemed a CSAUE.

We have found that employers' procedures in radiotherapy have not routinely defined 'clinically significant'. Services were not always able to provide examples of what would constitute as a clinically significant incident. We saw minimal reference of procedures to inform the referrer, practitioner and patient if a clinically significant unintended or accidental exposure occurred, and the outcome of the investigation was not always clearly outlined in incident policies.

Actions for employers

- Make sure your employer's procedures refer clearly to clinically significant exposures (CSAUEs). Procedures should clearly outline the process to inform the referrer, practitioner and patient and this should be adequately referenced in radiotherapy incident policies. Make all staff aware of the type of incidents that fall within the clinically significant category.

Themed inspection programmes

Our programme of themed inspections enables us to look in more detail at specific areas. This enables us to understand more following any trends we see in statutory notifications or from concerns that we find in our planned inspections. We can then make recommendations to employers to improve.

Neurointerventional imaging

In 2019, we published our guidance on the criteria for significant accidental and unintended exposures (SAUE). This introduced a category for notifying non-transient deterministic effects (also called tissue effects), regardless of whether they involved any errors. This is the effect of radiation on health, where the severity varies with the dose administered.

We first reported back on findings in our annual report for 2019/20, where we reported 10 notifications of skin injuries – all from neurointerventional procedures. Based on this, we initiated a programme of inspections to look at these specialist services as part of our graded approach. In England, there are 24 specialist centres in the NHS, and a further centre provided by an independent provider that opened in 2022.

We contacted 11 NHS trusts whose diagnostic imaging services we had previously inspected within the previous 7 years. Although these employers were not a priority for the inspection programme, we asked for some basic information that allowed us to support our findings and consider where we target future resources.

Notifications

We received 9 notifications of hair loss following these procedures in 2021/22. All 9 notifications came from 3 centres that carry out the most complex procedures under the specialty. When we reviewed them, we found all procedures were fully justified and their side effects were known, with patients giving consent where appropriate. However, learning was identified for all cases, including a raised awareness of the effects of the procedures.

Inspections

We developed an inspection programme, which started in 2019, specifically for the neurointerventional services of the 24 specialist NHS centres. We had inspected many trusts within the previous 7 years under other programmes, such as the paediatric programme from 2017 to 2019, so this neurointerventional programme prioritised the other centres. The programme involved 10 inspections between 2018 and 2022.

As a result of these inspections, we took enforcement action at 3 locations for breaches of Regulations 6, 8 and 17 and issued Improvement Notices relating to:

- poor quality training records
- poor quality assurance of documentation and failure to complete statutory notifications following recommendations from the medical physics expert.

None of these Notices linked directly to the neurointerventional departments themselves, but to general governance issues within radiology departments. See our [enforcement register](#) for more information on these notices.

What we found

There were some common themes from this inspection programme, although many may also be relevant to other cardiology or radiology interventional services.

Documentation

We regularly found that the employer's procedures were not representative of the practice carried out in the department. This was usually because they were more general in nature and intended to cover several services within a trust. For example:

- There was no reference to the WHO checklists in the patient identification procedure.
- The procedures to check for pregnancy did not take into account the tests carried out pre-operatively by admission nurses.
- The consent process for informing patients of the benefits and risks was not included in the relevant employer's procedure.

To address this, some employers had adopted local procedures covering the specific services in detail. These were sometimes developed alongside LOCSSIPs (local safety standards for invasive procedures).

Actions for employers

- Review your employer's procedures to make sure that they cover the range of services you provide.
- Make sure your employer's procedures are useful to staff.
- Consider adapting specific procedures or separate them from the high-level overall trust procedures.

Referral guidelines

Most neurointerventional services visited had not implemented referral guidelines. We have also seen this in cardiology inspections. The most common route for referrals was between specialist consultants or neuroradiologists occasionally acted in all 3 duty holder roles. Under IR(ME)R, referral guidelines, which include radiation doses, must still be made available to referrers.

Equipment

Ageing equipment was identified as a risk in 3 inspections, with some between 15 to 19 years old – well past its recommended life cycle. From the data requests to trusts, we identified a further two employers that also had ageing equipment

Although equipment replacement is not a direct requirement of IR(ME)R, it is important for employers to ensure equipment is replaced and updated as part of a planned programme. Ageing equipment does not have the latest new software and dose saving technologies, which offer significantly lower doses and enable exposures to be optimised effectively. There is also a potential risk, as seen during one inspection, from repeated equipment failures either causing procedures to be cancelled or patients to be moved to other labs.

The European Society of Radiology (ESR) recognised the clinical importance of planning for timely equipment replacement in its [2014 position paper](#) on renewal:

- equipment up to 5 years old reflects the current state of technology and offers opportunities for economically reasonable upgrade measures
- equipment between 6 and 10 years old is still fit for use if properly maintained, but already needs replacement strategies
- equipment older than 10 years is no longer state-of-the art and replacement is essential.

Actions for employers

- Make sure you have a proactive replacement programme that includes interventional equipment. Consider using a risk register to manage the risk for ageing equipment.
- To ensure the system is safe for its intended purpose, use professional guidance and manufacturers' recommendations to clearly define the criteria to consider when deciding to decommission equipment.
- Also consider quality assurance, and whether a more frequent testing schedule would be appropriate.

Patient doses

The 2021 report from the Committee on Medical Aspects of Radiation in the Environment (COMARE), [Radiation doses in interventional radiology: issues for patients and staff within the UK](#), identified that the lack of data about patient doses has delayed establishing national diagnostic reference levels (DRLs) for interventional radiology procedures. Because of the small numbers of procedures, which sometimes varied significantly between patients, it is difficult to develop local diagnostic reference levels. Nevertheless, all services we visited had adopted levels for a range of examinations. From the data requests, all but 4 employers have set local diagnostic reference levels. One had not because the equipment had only recently been installed and the employer was waiting to carry out a dose survey.

From our discussions during the inspections, we found only limited sharing or benchmarking of some of this data with other specialist services within the network. But of those that did share data, this was relatively comparable.

As well as carrying out standard dose audits, we saw examples of physicians leading more stringent audits including looking at reasons behind data outliers and comparing doses from different embolic materials.

Some services did not have skin dose policies. At the time of our inspection or data request, 6 employers had no formal policies covering neurointerventional services, or had only just introduced them.

Policies varied significantly in quality and used different levels to trigger certain follow-ups.

Formal action levels for observations during procedure, such as the ones recommended in the [COMARE report](#), were not commonplace. However, there was exceptional dose awareness – both during and after procedures – from all members of the multidisciplinary team.

The International Atomic Energy Agency is launching an [international study of patient doses and tissue reactions from fluoroscopy guided interventional procedures in 2022](#), to improve the amount of information relating to tissue reactions.

Actions for employers

- Make sure you're familiar with the [COMARE report](#) when carrying out any complex interventional imaging. Sharing information will enable benchmarking of protocols, data and optimisation to improve patient doses.
- Introduce or review skin dose policies to ensure they reflect up-to-date guidance and consider introducing action levels during a procedure as stated in table 7.3 of COMARE report.
- Consider participating in the International study of patient doses and tissue reactions from fluoroscopy guided interventional procedures and using the IAEA's SAFRAD system to increase the amount of international intelligence.

Mobile CT services

We have been trialling a programme of inspections on mobile CT services. The programme is in response to a risk identified during the pandemic where we became aware of a significant increase in the number of mobile CT units in the independent sector. Through notifications, we have seen unique risks to patients posed by the set-up of these services.

On our first inspection early in 2021, we visited the head office of a company to discuss with senior leaders the governance surrounding radiation protection. Six months after the original visit (delayed due to the further pandemic wave), we carried out 3 announced and 2 unannounced site visit inspections of the company.

The main findings from our inspections of this employer were unique to this type of service, and meant that we made a number of recommendations:

- Some parts of the patient pathway were shared with other employers, which meant the provider needed to rely on others to ensure duty holders were appropriately entitled and trained.

Under Regulation 6(2) the employer must ensure that all duty holders, including those entitled by host sites, are able to comply with written procedures.

- The rotation of staff between different host sites sometimes meant radiographers needed to use different examination protocols because of the variation in some examinations, such as CT liver and urograms. This had led to radiation incidents involving several patients who needed to be re-scanned at the trust using the required protocol. But the mobile CT service had limited ability to standardise protocols because of contractual agreements.

Under Regulation 6(4) the employer must ensure there are written protocols in place for every type of standard examination, and where possible, standardise these between host sites.

- Because of poor co-operation with host sites about reviewing and managing incidents, there were delays in concluding investigations and findings were not shared between employers. This also led to duplicated statutory notifications and delays in submitting reports of notifications to us.

Under Regulation 8(4) the employer must ensure there is a process for investigating and managing accidental or unintended exposures and should co-operate with host sites when carrying out these investigations.

- The nature of the service meant there were only limited clinical audits, with another employer carrying out much of the clinical evaluation and justification.

Under Regulation 7, the employer's procedures must include provision for carrying out clinical audit, which must be embedded within the governance programme.

We inspected another employer using this format in March 2022. Again, we visited the head office followed by 2 unannounced site visits. Some findings were similar to those of the other employer, although because this service was smaller in size there was less rotation of radiographers. This meant staff were more familiar with some site specifics such as protocols and employer's procedures.

However, we did find a number of breaches that resulted in 2 Improvement Notices.

We will continue this programme over the next 3 years because of the issues we have seen. Co-operation between employers is an area of focus as part of the community diagnostic centres and guidance on establishing an IR(ME)R framework. This will also support any memorandum of understanding or service level agreement for mobile services in a similar way. We also raised concerns with the clinical imaging board about the huge variation in some CT protocols.

Chiropractic inspections

In April 2022, we announced a programme of inspections to services run by chiropractors registered with the General Chiropractic Council (GCC). The aim of this 'snapshot' inspection programme was to increase our understanding of compliance standards within chiropractic using radiography, and to address the small number of historic concerns raised by the public or other healthcare professionals.

Although this is outside of the 2021/22 period for this annual report, we highlight some early feedback to acknowledge the poor level of compliance found from the initial 3 inspections.

Although subject to professional regulation from the General Chiropractic Council, chiropractors are exempt from registering with CQC under the Health and Social Care Act 2008. However, IR(ME)R still applies.

What we found

In general, compliance with IR(ME)R was poor. The first 2 inspections resulted in Improvement Notices. These required the employers to appoint a medical physics expert and/or to adopt diagnostic reference levels. You can see further information on these notices on our [enforcement register](#).

In other findings:

- Employer's procedures were generally incomplete and not maintained or regularly reviewed.
- The concept of referral guidelines was not understood and these were either unavailable or there were several different sets.

- Arrangements for quality assuring equipment varied from not happening at all to a visual inspection only, or a medical physics expert QA testing equipment once every 3 years.
- There were no records of practical or equipment training for chiropractors who took X-rays.
- In one case, there was no evidence of the use of collimation to reduce the amount of tissue exposed, and no DAP meter fitted, despite installing the X-ray set in February 2022.

We are keen to continue our pilot chiropractic inspection programme, as we remain concerned about poor compliance and understanding of IR(ME)R requirements among this profession.

We believe it is crucial for chiropractors to work closely with their medical physics experts. We will be sharing our concerns with the General Chiropractic Council and working together to improve compliance.

Other IR(ME)R related activity

Statutory instrument review

The Department of Health and Social Care must review the IR(ME)R regulations every 5 years. We have contributed suggestions for improvement to support the full review of the regulations, which are due to be released in the next year.