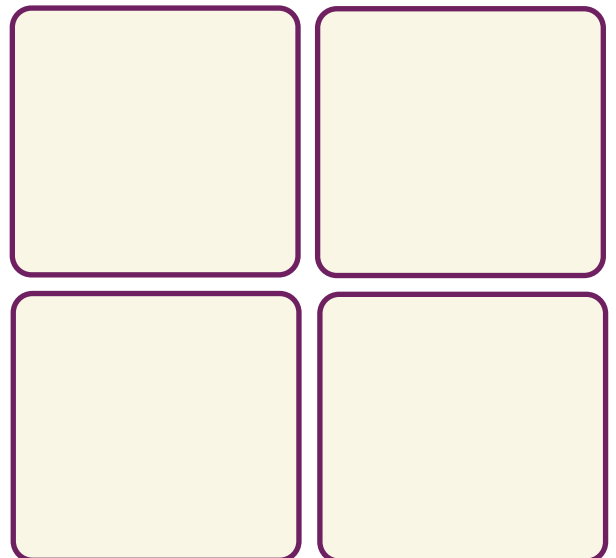


IR(ME)R annual report 2016

CQC's enforcement of the Ionising Radiation
(Medical Exposure) Regulations 2000

October 2017



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Introduction

The Ionising Radiation (Medical Exposure) Regulations, known as IR(ME)R, were established in 2000 to ensure that there was a regulatory framework to support the radiological protection of the patient. Medical exposures, such as those used in diagnosis, treatment, research and screening should be individually justified and optimised. The regulations were established in 2000, with amendments in 2006 and 2011 and were enacted to satisfy Council Directive 97/43/EURATOM.

The purpose of this report is to update and share with healthcare professionals the findings from our inspections and notifications of exposures 'much greater than intended', and what CQC has found in relation to compliance with the regulations. We feel this, in turn, should help providers to identify poor regulatory compliance and procedural failures in their own departments.

As with our previous reports, we provide a breakdown of the notifications of exposures much greater than intended that we received across the three medical radiation modalities: radiology, nuclear medicine and radiotherapy. We also present some examples for wider learning arising from our work.

The data in this report only reflects notification activity since CQC was formed in 2009.

CQC's activities in 2016

When we process notifications, we ask the provider for evidence that the incident has been fully investigated and that they have taken action to address any risks. We then email the provider to close off the notification formally. For more information of what we look for, please see our website. www.cqc.org.uk/guidance-providers/ionising-radiation/reporting-irmer-incidents.

As well as receiving and investigating notifications of exposures much greater than intended, inspections are an important part of our work. We conducted 16 IR(ME)R compliance and follow-up inspections of services, which, in some cases, were in response to concerns or notifications received that we judged to be 'high-risk'. The 16 inspections also included nine proactive inspections where the visit was not as a result of any concern, but was part of our planned inspection programme.

With two new clinical specialist inspectors in 2016, we have also been able to provide greater support to CQC's wider inspection programmes that enforce the Health and Social Care Act 2008.

To encourage consistency in reporting, we contributed to discussions with other IR(ME)R inspectorates, Public Health England and the Department of Health, to develop proposals and guidance for healthcare providers on making notifications of exposures much greater than intended. This was reflected in new guidance from the Department Of Health published in January 2017. We also continued to provide support to professional bodies concerning the categorisation of different types of error in radiology.

CQC hosted a visit from a partner enforcement authority from France, who had expressed an interest in our approach to enforcing IR(ME)R in England. This arose from our contribution to international meetings within the enforcement of medical radiation in Europe, known as HERCA (Heads of European Radiation Competent Authorities).

We also met with other IR(ME)R inspectorates from the UK and government agencies with an interest in radiation protection, including the Health and Safety Executive, Public Health England and the Medicines and Healthcare products Regulatory Agency at the Medical Radiation Liaison Group, chaired by the Department of Health. This activity will continue to increase as work progresses in the lead-up to the adoption of new regulations (designed to replace existing IR(ME)R and some other regulations) arising from Council Directive 2013/59/EURATOM, which must be transposed into UK law by February 2018.

Summary of findings

In 2016, we received a total of 1,319 notifications of exposures ‘much greater than intended’, which represents a 3.3% increase in total numbers from 2015. Of the 1,319 notifications:

- 1,069 (81% of the total, which shows no percentage change from 2015) were from **diagnostic radiology** departments. As in 2015, the most common error reported to us was when the ‘wrong patient’ was referred for imaging or was improperly identified by staff working within the imaging department. That remains the case this year at 30% of the sub-total within radiology, almost unchanged since 2015.
- 61 notifications were from **nuclear medicine** departments, which is an increase of 17% from the 52 we reported in 2015. In 2016, as with the previous year, we received only two notifications of therapeutic nuclear medicine errors.
- 189 notifications were from **radiotherapy** departments. Of these cases, 118 were categorised as ‘radiotherapy imaging’. This left 71 notifications related to treatment errors, which was broadly in line with previous years.

We attribute the increase in overall notifications in 2016 to the estimated increase in annual activity. We have no reason to believe that practice is poor, but rather we feel that governance and incident reporting cultures are improving.

However, we continue to be concerned that patient identification errors are still the highest category of notification, which suggests little learning year on year in addressing this issue. Despite the pause and check procedure being in place since 2015, we still feel that errors are occurring because of a lack of adherence to this patient safety measure. We also have concerns around a lack of understanding of IR(ME)R, especially relating to authorisation, justification, clinical audit, training requirements for all duty holders, and diagnostic reference levels.

New regulations will be in force by February 2018. We feel this is an ideal opportunity for departments to re-evaluate the governance processes around the regulatory framework and associated culture. Clinical staff need to be more aware of their roles and responsibilities under IR(ME)R and there needs to be a more collaborative approach between the employer, medical physics experts and clinical staff.

The demand for imaging and radiotherapy continues to rise and departments are pressured environments. However, patient safety must remain a priority, which includes adhering to regulations and professional standards.

As well as wider learning themes in relation to notifications and safer medical exposure practice, we have seen the following examples of good practice, which organisations can learn from and adapt.

Examples of good practice

To address referrer errors such as requesting a radiological examination on the wrong patient, one NHS acute trust has developed a template to complete in addition to the usual trust incident report. This includes a root cause analysis on what occurred and why, and whether the trust's patient identification procedure was followed. It also includes reflection by the referrer and details the remedial actions put in place by the clinical team. The trust's clinical risk committee sees this as a useful way of addressing unnecessary medical exposures.

Another NHS trust has established a paediatric imaging optimisation group in response to a notification and enforcement action due to a lack of optimisation and training for paediatric imaging. The group meets regularly to review: patient doses in paediatric radiology, training, image quality, innovative practice and new techniques, evidence-based imaging and patient experiences. The result was an improvement in standards and standardised practice across the trust, with additional benefits after a similar group was established in adult radiology.

The 'pause and check' initiative in radiology has now been extended into radiotherapy with suitable templates suggested by the Society and College of Radiographers. We have noted that some nuclear medicine departments have also introduced similar guidance and/or posters to reduce the risks of unnecessary scans or injecting incorrect radiopharmaceuticals.

We have seen the introduction of 'human factors engineering' to reduce errors in some radiography and radiotherapy departments. In one trust, following incidents in radiotherapy, joint working between departments included workshops for radiographic staff in basic understanding of how mistakes are made and what can be done to try to minimise them.

Working within a team is relevant in all modalities of medical exposure, particularly along the radiotherapy planning and treatment pathway. We have noted the benefits when representatives from the whole multidisciplinary process are involved in incident reviews. This includes management, clinicians, radiographers, scientific, engineering and other support staff. Involving different professionals in what is often a multi-faceted error can be particularly beneficial, despite the impact on staff time.

Overview of notifications of exposures 'much greater than intended' in 2016

Regulation 4(5) requires employers to notify CQC of exposures of medical ionising radiation that are much greater than intended, resulting from procedural failures rather than equipment malfunction. In 2016, we received a total of 1,319 notifications, which represents a 3.3% increase in total numbers from 2015.

Figure 1 shows the percentage increase of the annual number of notifications year on year.

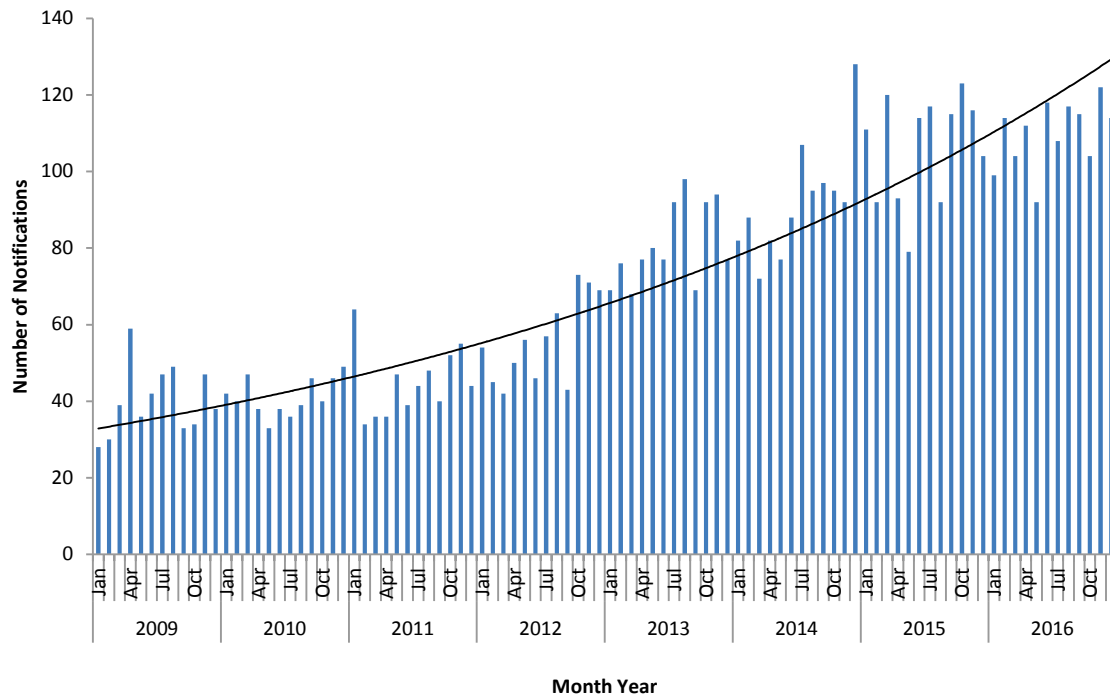
Figure 1: Total notifications received, 2009 to 2016								
Organisation type	2009	2010	2011	2012	2013	2014	2015	2016
NHS acute	457	460	514	638	918	1,060	1,210	1,219
Independent hospital	19	28	22	28	47	38	63	96
Other (including primary medical & dental)	6	6	3	3	4	5	4	4
Total number notifications	482	494	539	669	969	1,103	1,277	1,319
Percentage change		2.5%	9.1%	24.1%	44.8%	13.8%	15.8%	3.3%

Source: CQC notifications data.

In our report for 2015, we showed a distribution of notifications from radiology departments in the public and independent sectors. Broadly speaking, the breakdown is comparable this year, apart from a steady increase in notifications from the independent sector. It is difficult to explain this recent increase, though it is likely to be connected with improved governance in line with increased inspection activity of the independent acute sector, both through IR(ME)R compliance and wider comprehensive inspections, and perhaps coupled with better communication between these providers and their medical physics expert.

Figure 2 on the next page illustrates a steady increase over consecutive years of the total numbers of notifications received monthly since 2009. This is in line with an increasingly positive reporting culture (the desire to report and learn) seen across many healthcare providers.

Figure 2: Monthly rates of notifications 2009 to 2016



Source: CQC notifications data.

Comparisons with ‘activity’

While the overall increase in notifications since 2015 is only 3.3%, this should be put alongside the changes in ‘activity’ – the numbers of medical exposures taken in the country over the same period. We are aware that there is no centralised data collection of activity for the independent sector in either the acute hospital or primary care setting. This has made it difficult to analyse data relating to these areas.

The most reliable activity data for NHS acute hospital services is provided by NHS England, called the [Diagnostic Imaging Dataset \(DID\)](#).^{*} Overall, this shows an increase in activity. The number of plain X-rays is largely comparable with 2015; the numbers of more complex studies in MRI, CT and PET-CT (the latter arising from the roll-out of the national PET-CT contract) has led to an overall 3% increase in NHS imaging activity since last year. This tells us that there has been a comparable increase in notifications in this last year. Similar data is available on the NHS England website describing the numbers of dental X-rays taken of adults and children.

We can therefore attribute the 3.3% increase of overall notification numbers in 2016 to the estimated increase in annual activity of around 3%. We have no reason to believe that practice is poor, but rather we feel that governance and incident reporting cultures continue to improve.

^{*} <https://www.england.nhs.uk/statistics/statistical-work-areas/diagnostic-imaging-dataset/>.

However, patient identification errors remain the largest notification cause, which indicates that there has potentially been limited learning since we highlighted this in the 2015 report. The National Cancer Registration and Analysis Service (NCRAS) is responsible for the [Radiotherapy Dataset \(RTDS\)](#)^{*}, which covers all activity within the NHS. This dataset measures activity differently where activity is measured in 'episodes'. A radiotherapy episode is a continuous period of care for radiotherapy, including all preparation, planning and delivery of radiotherapy. In 2015/2016, there were around 133,000 episodes, which was a small decrease of 0.5% in radiotherapy activity compared with the previous year.

Trusts that made no notifications in 2016

In our 2015 IR(ME)R report, we explained that we were aware that a number of organisations had not made a notification to us in that calendar year. This could be viewed as a positive finding demonstrating a good safety culture. However, it is more our view that in radiology departments, with increased demand and higher activity levels, having zero incidents is unlikely. This is a potential risk and in this report, we identify the organisations that had not notified us of any notifications.

There were 16 NHS trusts with no notifications in 2016 (figure 3). The IR(ME)R team carried out a separate review of these trusts and looked at the trusts' overall CQC rating arising from their most recent comprehensive inspection.

We could find no apparent link between rating and expected notifications.

We will continue to monitor these trusts, meet and discuss the findings, and agree next steps with colleagues in CQC who have oversight of providers. The list does not include non-acute NHS organisations or organisations in the independent sector.

When analysing these trusts, we believe it is important to consider the following explanations:

1. The analysis does not take account of 'activity'. Several of the trusts in the list would be characterised as 'very low' activity in terms of the numbers of X-rays and scans involving ionising radiation carried out monthly; therefore no notifications in a calendar year could be attributed to this low activity.
2. Five of those listed have made a notification in the first four months of 2017.
3. Although one trust thought they were disclosing errors to CQC in 2016, they were not using the online IR(ME)R notifications portal, so were not counted. However, the notifications have now been received and this anomaly has since been corrected.
4. One of the trusts has since merged with another.
5. Looking further back into 2015 and 2014, we note that four of those listed had also not made a notification for the previous three years.

* http://www.ncin.org.uk/collecting_and_using_data/rtds.

Figure 3: NHS acute trusts that made no notifications to CQC in 2016

Trust name	Relevant detail
Alder Hey Children’s NHS Foundation Trust	(2, 3, 5)
Birmingham Women’s NHS Foundation Trust	(4)
Burton Hospitals NHS Foundation Trust	
Calderdale and Huddersfield NHS Foundation Trust	
Frimley Health NHS Foundation Trust	(2)
Liverpool Heart and Chest NHS Foundation Trust	(2, 5)
Liverpool Women’s NHS Foundation Trust	(1, 5)
Moorfields Eye Hospital NHS Foundation Trust	(1, 5)
Queen Victoria Hospital NHS Foundation Trust	
Salisbury NHS Foundation Trust	
Sheffield Children’s NHS Foundation Trust	
Southport and Ormskirk Hospital NHS Trust	(2)
Tameside Hospital NHS Foundation Trust	
The Princess Alexandra Hospital NHS Trust	(2)
The Robert Jones and Agnes Hunt Orthopaedic Hospital NHS Foundation Trust	
The Royal Orthopaedic Hospital NHS Foundation Trust	

Source: CQC notifications data.

Note: The numbers in brackets refer to the numbered explanatory paragraphs above.

DIAGNOSTIC RADIOLOGY

In 2016, we received 1,069 notifications following errors that led to patients receiving exposures much greater than intended in diagnostic radiology, which, like most previous years, comprises around 81% of the total numbers of notifications across all modalities.

The increasing number of notifications should be seen in the context of data from NHS England, which shows that the numbers of radiology exposures have increased by nearly 3%.

Figure 4 on the next page provides a breakdown of the source of errors made in diagnostic radiology exposure.

Figure 4: Notifications from radiology, since 2009

Organisation type	2009	2010	2011	2012	2013	2014	2015	2016
NHS acute	374	380	424	535	736	867	975	993
Independent hospital	19	24	18	25	42	28	48	72
Other	6	6	3	3	4	5	4	4
Total number notifications	399	410	445	563	782	900	1,027	1,069

Source: CQC notifications data.

The NHS England report shows that there were around 41 million imaging tests overall in the NHS acute sector in 2016 (an increase of 1 million tests compared with data provided in our 2015 report). This included approximately 22.6 million X-rays (almost unchanged in the year), 4.6 million CT scans (up from 4.2million reported in last year's report) and over 1 million fluoroscopy examinations (almost unchanged since our 2015 report). There were also approximately 16.3 million dental X-rays taken in the NHS.

We would expect to see an increase in activity across the independent acute and primary care settings. However, for these sectors, there is no central reporting structure or publicly available data for the numbers of exposures taken.

Figure 5: Sub modality of diagnostic radiology notifications in 2015 and 2016

Sub modality of notification	Number of notifications in 2015	Number of notifications in 2016
CT	571	641
Radiology using film/CR/DR	400	369
Mammography	17	34
Dental	14	8
General fluoroscopy	14	6
Cardiac	4	4
Interventional radiology	4	4
DXA	3	3
Total	1,027	1,069

Source: CQC notifications data.

It is worth drawing attention to the fact that the number of X-rays compared with CT scans reported by NHS England is not mirrored in their respective number of notifications. This is due to the differences in the thresholds when deciding whether an error is ‘much greater than intended’. For example, under PM 77, X-ray errors were reportable above 10 or 20 times the intended dose (depending on body part) and CT errors over 1.5 times the intended dose. However, the Department of Health’s new guidance has changed some of these thresholds, so we do not expect figures from 2017 to reflect those from previous years.

As seen in figure 5, there have been few errors reported from dental X-rays (eight in 16.3 million). We feel this can be attributed to the fact that most dental practices will have a limited number of notifications that need to be reported. This is likely to be because the referrer, practitioner and operator are generally the same person and therefore there will be fewer ID errors, but also because the dose thresholds in dentistry are unlikely to be met.

In 2016, there was a continued steady rise in the proportion of radiology notifications of errors involving CT scans, alongside a small reduction in notifications in errors involving ‘plain radiography’. This is alongside the overall modest increase in activity within the same period, as reported by NHS England. Figure 6 shows the types of error in radiology departments.

Figure 6: Analysis of errors in radiology departments (notifications in 2016)

Type of error	Number of notifications	% of total
Referrer error – wrong patient	221	20.7%
Operator error – wrong anatomy/laterality	177	16.6%
Operator error wrong exposure set	155	14.5%
Operator error – failure to ID patient	101	9.4%
Operator error – no check back of previous imaging	95	8.9%
Timing error for examination/booking/NGT timing	86	8.0%
Referrer error – no check back	62	5.8%
Referrer error – wrong anatomy or modality	55	5.1%
Operator error – incorrect modality selection	39	3.6%
Operator error – other	29	2.7%
Operator error – image archive/labelling	28	2.6%
Voluntary notification	17	1.6%
Referrer error – other	4	0.4%
Total diagnostic radiology notifications	1,069	

Source: CQC notifications data.

Note: When calculating the percentage we have used the total notifications from diagnostic radiology as the denominator.

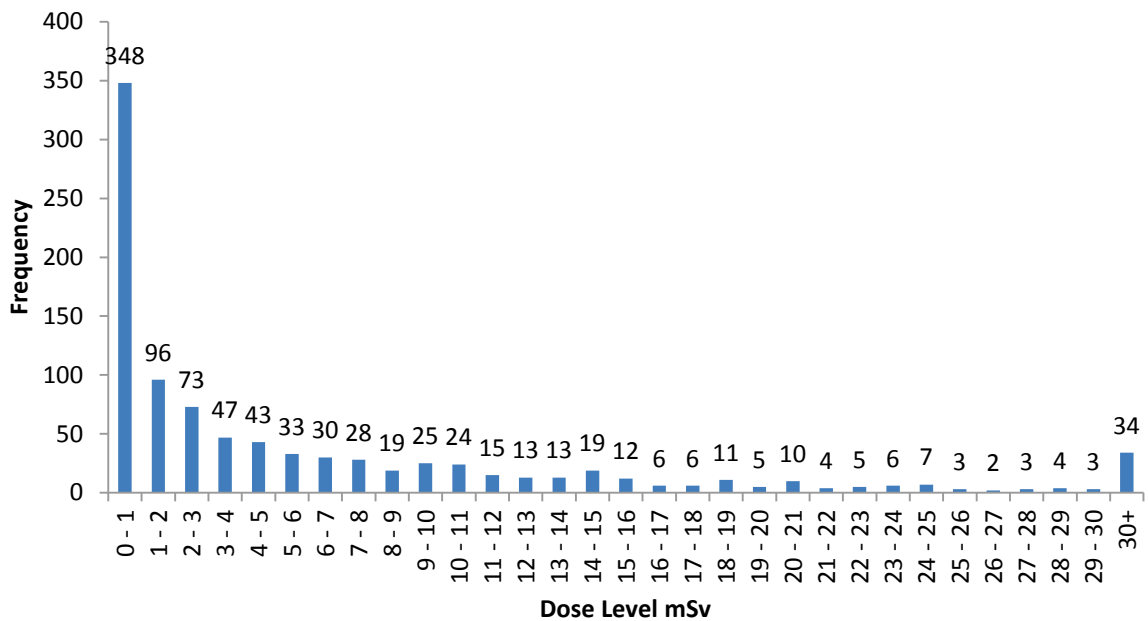
Figure 7: Percentage of notifications of CT scans as a proportion of those from radiology as a whole

2009	2010	2011	2012	2013	2014	2015	2016
43%	43%	42%	48%	56%	57%	56%	60%

Source: CQC notifications data.

Figure 8 shows the frequency of reported patient doses for errors in diagnostic radiology exposures in 2016. The overall distribution of the effective dose value (provided by the notifier, or estimated by CQC) remains broadly similar to that from previous years. Figure 8 also shows that the majority (36.7%) of all our notifications in radiology result in an effective dose of 0-1mSv, and only a very small proportion of our notifications (3.6%) deliver a dose of 30mSv or greater.

Figure 8: Distribution of patient doses from radiology notifications in 2016



Source: CQC notifications data.

There is a small increase in the number of errors where the dose reported to us is less than 30mSv. We are aware of an inconsistency in this number and remind those submitting this data that the notification should be for the dose delivered in error rather than the sum of the error dose and the intended dose.

These dose levels should be compared with the average dose (approximately 2.7mSv), which the UK population receives annually from natural ‘background’ radiation.*

* <https://www.gov.uk/government/publications/ionising-radiation-dose-comparisons/ionising-radiation-dose-comparisons>

Key findings from notifications and IR(ME)R inspections

The following are some key themes that arose from our work in radiology in 2016, which we hope will help providers to learn from and improve their own compliance locally.

Key findings from notifications

Inappropriate induction and equipment training for agency staff: A number of notifications in 2016 related to inadequate training for agency staff. The expectation is that, as well as being able to demonstrate training records through their agency, all agency staff should also undertake a local equipment competency assessment. It is imperative that providers can assure themselves of the radiographer's competence before they are left to work unsupervised.

Lack of training in IT ordering systems and e-referral systems for referrers: There seems to be a disparity between how different providers train referrers to use e-referral systems. We also have ongoing concerns around the lack of robust processes for cancelling electronic requests when messages do not pass from e-requesting software to radiology information systems.

Failure to check previous imaging: All duty holders have a shared responsibility to check previous imaging before taking a medical exposure. This ensures that patients do not undergo unintended imaging due to duplicate referrals or superseded examinations.

Lack of understanding of care pathways and guidance in mammography: In 2016, we saw an increased number of mammography errors. These have generally involved patients undergoing symptomatic mammograms under the age of 40 when ultrasound is recommended, or patients having symptomatic and screening mammograms within six months of each other because of a failure to check previous imaging dates.

Continued operator errors involving the use of equipment: These include wrong detector selection and misuse of override controls. We have also seen that when operators rely on the settings on control panels in plain film, it has caused over-exposure because of a failure to optimise or change the manufacturer settings and adjust back up timer parameters.

Inappropriate optimisation: We have seen evidence of radiographers and other members of staff altering protocols, exposures and density settings, with varied input from the medical physics expert and manufacturer's applications specialists. This has often led to incorrect protocol set-up and selection and adversely affected optimisation of exposures in line with the ALARP (as low as reasonably practicable) principle.

Availability of referrals to staff: A number of incidents have involved radiographers undertaking identification and examination checks without having sight of the request. This has led to some patients being wrongly identified or the wrong examination being performed.

No pause and check: We still see a high number of errors where pause and check has been disregarded or forgotten, which might have been avoided if this process was undertaken for every

patient examination. There is strong evidence from the National Patient Safety Agency and other bodies that the use of processes such as pause and check reduces the risk of error.

Lack of supervision of staff: A number of incidents have involved the poor supervision of staff undergoing training, including student radiographers.

Key findings from IR(ME)R inspections

Confusion between authorisation and justification: We again ask that responsible radiographers look at their local procedures to ensure that staff entitled as IR(ME)R practitioners in their own right or authorising under guidelines issued by a practitioner are aware of their tasks and responsibilities and are adequately trained.

Lack of training records: Documented equipment training is key for all members of staff for all equipment they operate. This may be tailored to what each duty holder specifically uses rather than a comprehensive training package. Practitioners must also be trained specifically to their scope of practice. Regulations clearly state that these records must be available for inspection.

Misunderstanding of diagnostic reference levels (DRLs) and doses: While we see in most departments that DRLs are displayed in controlled areas, there seems to be a lack of understanding among radiographers of how DRLs should be used and how to monitor when levels are consistently exceeded.

Responsibility for tasks involving multiple operators/practitioners: We have sometimes found that individual responsibility for carrying out tasks such as identifying patients, checking for pregnancy, and checking for previous imaging is not always clear, especially when there are multiple members of staff working together.

Unclear employer's responsibilities and governance frameworks: Employers are not always aware of their responsibilities and the general requirements of IR(ME)R. This is because of unclear governance frameworks and the failure of escalation of issues raised at radiation protection committees and reportable notifications. This is particularly important where there is a third party involved and it must be clear who the employer is and which procedures should be followed.

Key findings from comprehensive inspections

The following are some key themes from our comprehensive inspection work in radiology in 2016, which we hope will help providers to improve their own compliance locally.

Duty of Candour: We have seen a greater awareness of the duty of candour within radiology departments. The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person. This has improved since our previous report

Accreditation: Many departments are in the early phases of seeking accreditation with the Imaging Services Accreditation Scheme (ISAS). This process has helped departments in improving their governance structures and audit processes.

Benchmarking: A number of NHS trusts are using NHS Benchmarking, which has helped to identify areas for service improvement. The data has also been used to support business cases.

Image reporting: In 2016, we inspected a trust that had a large reporting backlog of images, particularly plain film, which resulted in us taking enforcement action using our powers under the Health and Social Care Act. We have heard of other trusts that have experienced a backlog of image reporting, and continue to investigate them as appropriate.

Demand and capacity: We are aware of a year-on-year increase in the demand for radiology services nationally and changes to some NICE guidelines that involve additional CT imaging requirements. This may be compounded by a continued national shortage of many staff groups within radiology and diagnostic imaging. We continue to see outsourcing of reporting to meet the demand.

Equipment replacement: In 2016, we have seen continued use of ageing equipment, especially in sites that cannot afford, or justify, the expense of a new system. Some providers have cited this as a risk and have developed associated action plans.

Medical physics experts: We have seen variation in practice across both the independent sector and the NHS, especially in relation to the input and consultation with the medical physics expert, especially if this is a third party arrangement.

Enforcement action in 2016

In 2016, we served five improvement notices under IR(ME)R through our programme of planned inspections and reactive visits following notifications that we considered to carry a higher risk. This is an increase on the number served in previous years. We attribute this to the increased capacity within our IR(ME)R team, which enabled us to carry out more inspections and more detailed investigations of notifications of exposures much greater than intended. In summary these five enforcement notices related to:

- poor governance surrounding use of a mini C-arm
- inadequate training of a radiographer to undertake paediatric skeletal surveys and not optimising paediatric X-ray units
- inadequate training and entitlement of CT agency radiographers
- poor identification of referrers and quality assurance of procedures, absence of a clinical audit programme and incomplete training records
- incomplete training records and absence of a clinical audit programme.

There is further information about this on our website: <http://www.cqc.org.uk/content/our-enforcement-under-irmer>.

NUCLEAR MEDICINE

In 2016, we received 61 notifications from nuclear medicine departments, which is a 17% increase from 2015.

Figure 9 shows how the number of notifications has changed since we began collecting this information and the source of the notification (either NHS or independent sector) since 2009.

Figure 9: Nuclear medicine notifications 2009 to 2016

Organisation type	2009	2010	2011	2012	2013	2014	2015	2016
NHS acute	32	25	24	38	46	48	47	52
Independent hospital/other	0	1	1	1	4	7	5	9
Total number notifications	32	26	25	39	50	55	52	61

Source: CQC notifications data.

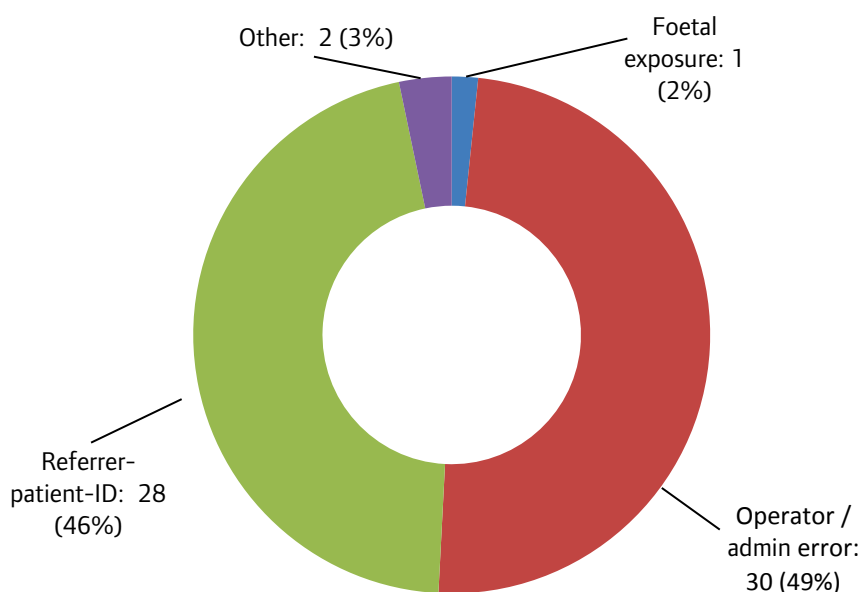
The NHS England Diagnostic Imaging Dataset has shown a 4.7% increase in nuclear medicine activity between 2015 and 2016. In 2016 there were around 420,000 examinations in nuclear medicine, 123,000 in Positron Emission Tomography (PET-CT) and 30,000 Single Photon Emission Computed Tomography (SPECT) examinations.

The categories of error in 2016 were comparable with previous years in terms of 'referrer' and 'operator/administration' errors.

The breakdown between diagnostic and therapy nuclear medicine exposures was again typical, and in 2016 we received just two notifications arising from radionuclide therapy.

Key findings from notifications and inspections

Figure 10: Type of error (nuclear medicine 2016)



Source: CQC notifications data.

Therapy nuclear medicine: Fortunately there are very few notifications arising from incidents in radionuclide or ‘molecular’ therapy each year, with just two received in 2016. By their nature these are relatively high risk and usually multidisciplinary, often involving oncology, nuclear medicine and medical physics staff. Therapy incidents may arise for example, from administration of excess or unnecessary radioactivity or in the timing or number of treatment occasions. To guard against such risks, we have found that good cooperation and communication across the team, together with identified responsibilities, procedures and rigid checking processes, is essential.

Training and competency in PET-CT: Some of the highest doses in diagnostic imaging occur in PET-CT, which is used widely across the independent sector and NHS. This modality accounted for over a fifth of the nuclear medicine notifications we received in 2016. Many of these were associated with operator error, hardware/software difficulties, image reconstruction, registration or management problems, plus errors in protocol selection and image archival. A priority in this technology and relatively high dose modality is to ensure comprehensive operator training and competency assessment, with supervision and back-up as appropriate.

Vigilance in minimising patient identity errors: Similar to diagnostic radiology, 46% (28) of the 61 notifications in nuclear medicine arose from the wrong patient being referred for a procedure. Most providers address this proactively following the recommendation from the Society and College of Radiography to use pause and check. Continued emphasis and reminders from the nuclear medicine department can help to implement the learning among referrers, whether it be through doctors’ induction, e-referral training, software prompts, medical bulletin reports or pause and check methodology.

Cancellation of existing referrals: If a patient’s management or treatment has changed or if staff realise that a referral has been made in error, it should lead to a cancellation of a request. However, some of these cancellations are often not actioned and the examination goes ahead. Robust arrangements for cancelling referrals therefore need to be agreed with referrers.

Operator authorisation according to practitioner guidelines: Where it is not practicable for the practitioner to authorise an exposure, an operator can do so “in accordance with guidelines issued by the practitioner”, which is an important facility generally within IR(ME)R. However, in our investigations of notifications in nuclear medicine, we have noted significant variation in the nature and detail of guidelines, an occasional lack of clarity and, in isolated circumstances, whether they actually exist. Guidelines should be clear and relevant to the task.

Wrong radiopharmaceutical (RMP) administered: In 2016, we received a number of notifications arising from patients being administered with the wrong RMP. Good laboratory management and practice is essential in nuclear medicine to avoid flawed ‘drawing up’, selection or injection of the wrong agent. A check of RMP identity needs to be an integral part of the injection or administration procedure (see below).

Final checks before administering RMP: A check of patient identity is required in IR(ME)R but in nuclear medicine there is also the need to check that the correct RMP and activity is being injected for the required examination. Checking processes may vary but an integrated four or five-point check, ideally immediately prior to injection, of: patient identity v. demographics v. protocolled request v. RMP v. dose, can act as a ‘fail-safe’ final check.

RADIOTHERAPY

In 2016 we received 189 notifications relating to radiotherapy.

Figure 11 shows how the numbers of notifications from radiotherapy departments in NHS and independent hospitals has changed since 2009.

Figure 11: Radiotherapy notifications 2009 to 2016

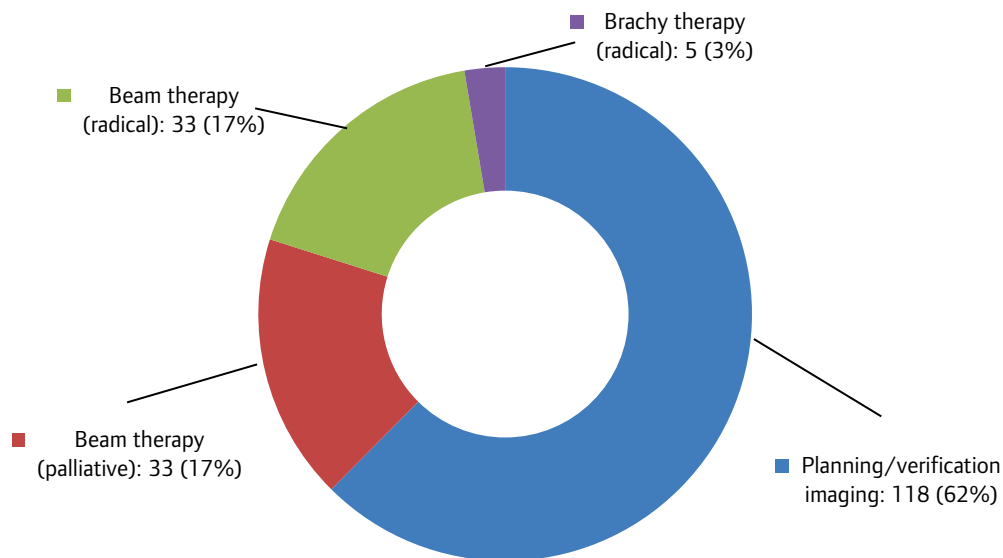
Organisation type	2009	2010	2011	2012	2013	2014	2015	2016
NHS acute	51	55	66	65	136	145	188	174
Independent hospital		3	3	2	1	3	10	15
Total number notifications	51	58	69	67	137 (73)	148 (76)	198 (130)	189 (118)

Source: CQC notifications data.

Note: The figures in brackets indicate the number of radiotherapy imaging error notifications (planning and verification).

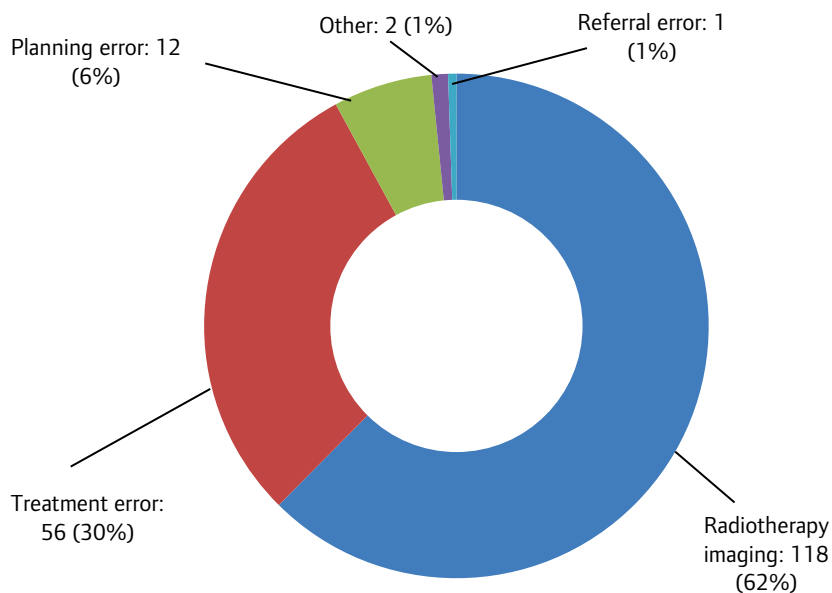
The number of treatment exposures notified to us has remained largely consistent over the past four years at around 70 a year. We have drawn attention to a variation in reporting practice in radiotherapy imaging in previous reports.

Figure 12: Sub-modality of notifications (radiotherapy 2016)



Source: CQC notifications data.

Figure 13: Type of error (radiotherapy 2016)



Source: CQC notifications data.

Key findings from notifications and inspections

The following are some key themes that arose from our work in radiotherapy in 2016, which we hope will help providers to learn from, and improve, their own compliance locally.

Radiotherapy imaging

Failures in imaging protocol and anatomy coverage: Of the 118 imaging notifications, approximately two thirds related to errors or procedural difficulties in radiotherapy imaging. Of these, by far the most common error was a failure in imaging protocol or failure to scan adequate anatomy that would assist optimum planning of the clinical oncologist's treatment intent for each. In most cases, such errors led to the need for a new or repeat planning scan. Errors and root causes were varied but included:

- incorrect patient positioning
- operator selecting incorrect or too restrictive scan limits
- operator selecting the wrong imaging protocol
- operator misinterpreting or making a mistake in reading the request, or miscommunication between the operator and referrer
- clinical oncologist providing inadequate or incorrect clinical information.

Although under IR(ME)R there is a requirement for imaging protocols to be in place, it appears that at a practical level many planning scans, even though subject to protocol, may have additional patient-specific requirements. Whether 'on' or 'off' protocol, it is essential that the clinical oncologist's referral is sufficiently detailed, with accurate and clear instruction on what is required of the planning scan. The operator must take careful account of all the clinical detail and information in the planning request and raise a query with the referrer if there is any uncertainty on what is required.

Machine difficulties or forgotten accessories: The following complications have resulted in the need for a repeat scan in approximate order of importance:

- the radiographer did not operate the CT scanner appropriately, or used the wrong breast board, or made +/- directional errors
- difficulties with immobilisation devices and preparation of the patient including bolus, dentures, mouth bites, patient clothing etc.
- forgotten contrast, inappropriate bladder status or filling
- missing or incorrect markers, scar wiring.

Unnecessary or unintended planning scans: At times, a planning scan is carried out when it is not required even when there has been no breakdown in procedure, for example, the patient's condition may have changed and treatment cancelled intentionally. Occasionally, a patient undergoes scanning, but evidence then confirms that there is no medical need for radiotherapy. In some cases, the patient may have been admitted by mistake into the planning pathway and

there should be learning and control measures to reduce the likelihood of such events. All duty holders have a shared responsibility to ensure that scanning is only performed when planning and treatment are to follow.

Verification - use of wrong reference image: For example, an incorrect image transferred from planning, or an image selected from the wrong patient file, which nullifies the verification process and an unnecessary verification exposure.

Radiotherapy treatment

We received 71 notifications over 2016 relating to errors in treatment, which is consistent with the past four years. The breakdown in type of error was also typical of that seen previously, in particular with approximately equal numbers of overdose and geographical miss treatment incidents. In terms of treatment modality, with just five notifications arising from brachytherapy, the majority of notifications were divided between palliative (33 notifications) and radical (33 notifications) beam therapy. We summarise the key findings below.

Unnecessary or flawed entry to treatment: Unnecessary planning fortunately rarely escalates to unnecessary treatment exposure. However, in 2016 there were two such notifications, one involving the whole course of treatment. A patient was externally referred as an emergency after a radiological diagnosis of metastatic cord compression with rapidly deteriorating neurological symptoms. He was transferred to the cancer hospital the next day and immediately underwent planning and received the first of five fractions of radiotherapy with the others following daily. It only emerged afterwards that the patient did not have cancer and the radiotherapy was unnecessary. Any learning and remedial actions from these unfortunate medical errors generally lie elsewhere and there is little scope within radiotherapy, except always to be alert to the possibility of medical errors in the external diagnosis and to ensure that referral criteria for treatment are met.

Referral and prescription errors: We receive a few of these notifications each year, but as above, they are relatively high-risk with the potential to remain undetected through the course of treatment. Errors may be related to dose and/or fraction or perhaps the wrong protocol. One notification in 2016 involved an electron treatment where, because of the anatomy, there was significant enhanced dose at the bone/tissue interface, which the practitioner and planner did not notice at the time of prescribing and planning treatment. With hindsight, it was recognised that this was not the appropriate modality and photons should have been used instead, but the wider department learned from the notification. As with operators, the practitioners can also adopt pause and check methodology and it is crucial to have a culture in the department that encourages open challenge across multidisciplinary team members to minimise such errors.

Over-exposure notifications: These notifications were generally in line with the long-established multiplication factors of 1.1 and 1.2 for whole course and single fractions respectively. Several notifications did not meet the recommended trigger levels for external reporting and were reported as 'voluntary' notifications. These included incidents where the outcome was actually an under dose in treatment. For over exposures, the root causes or principal contributory factors can arise from referral, prescription, planning, and during treatment as summarised below:

- incorrect set-up instructions or failure to follow them
- incorrect couch height and missed or wrong shifts, or failure to return the treatment couch to its original position
- incorrect patient/field positioning including limbs, leading to over-exposure of the target volume or exposure of unintended anatomy
- monitor unit or other calculation errors with learning on maintaining competency, quiet working and second independent checking
- incorrect calibration data, for example, in electron cut out factor, or in radioactive seed activity or treatment applicator factor.

Geographical misses in treatment: These most often occur for a single fraction before the error is realised. We have noticed that providers use a range of practice in deciding whether the miss is notifiable to us. Where there is a complete geographical miss, providers appear to notify us automatically, but the decision whether to report externally tends to take into account the displacement and size of treatment field, together with the dose. The Department of Health published more guidance in this area in 2016. Missing the intended target can arise in planning or pre-treatment or on set. The reasons are summarised below in approximate order of frequency:

- couch errors, including missed or wrong move or failure to return to original height or incorrect focus to skin distance setting between phases of treatment
- matching to the wrong vertebrae during online image review
- a missed move, incorrect size or wrong direction of shift by treatment staff, or occasionally arising from planning or set up instruction error
- treatment staff using the wrong tattoo or reference point in setting up treatment position
- incorrect skin site marked or acetate sheet wrongly annotated, leading to complete or partial geographical miss. At mark-up in clinic, it is essential to have external referral information including clear diagram and annotation of anatomical landmarks, together with multidisciplinary input on agreeing the treatment site
- treatment staff using an incorrect applicator, end frame or cut out, with particular difficulties in skin treatment
- patient with prostate cancer treated with the plan of another patient for one fraction, which highlights that patient identity checks need to include relevant imaging and planning files.

There is varied learning from such errors, which ranges from the operator reflecting on an isolated lapse, or recognising the need for a strengthened process or checking, for example, including the 'verbalisation' of moves, or providing additional training on image review and matching of anatomy.

Where there is a failure in the wider system, this may need to involve staffing arrangements, skill mix, specialist/senior support, additional checking mechanisms, or refresher training to improve. A recurring theme is the need to seek advice when in doubt, particularly in image matching where the learning from errors has shown that having a larger field of view shows more anatomy, which offers a better chance of an accurate match.

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