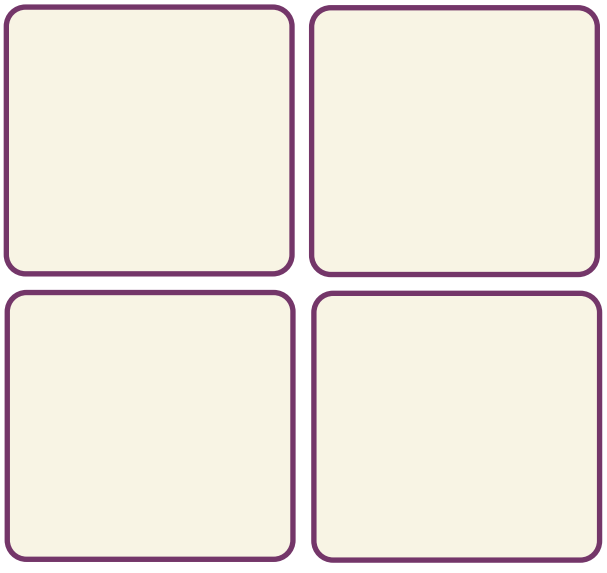
IR(ME)R annual report for 2015

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



November 2016

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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.

This is CQC's ninth annual report of our activity in enforcing the regulations. It is primarily to inform healthcare professionals and those with responsibilities for radiation protection of the patient in their own organisation. It is often regarded as a 'technical report', providing views from the enforcement authority about compliance with the regulations, and drawing attention to shortcomings and our enforcement actions.

In this report, we provide a breakdown of the notifications of exposures that were 'much greater than intended', which were notified to us across all medical radiation modalities. The notifications are divided by 'modality', which is how we describe the type of radiation exposure, and whether it was received as a result of errors in radiology, nuclear medicine or radiotherapy exposures. We also present some opportunities for wider learning.

Summary of activity in 2015

As well as receiving and investigating notifications, inspections are an important part of our work. We conducted five IR(ME)R compliance inspections and follow-up inspections of services in response to concerns or notifications received that we judged to be 'high-risk'. These inspections included treatment exposures delivered in error. In the first, a patient receiving nuclear medicine was injected with 50% more I-131 activity than was intended as part of their thyrotoxicosis treatment; and in another, an error in radiotherapy treatment to the skin led to unexpected hair loss arising from inadequate shielding. In these follow-up inspections, we visited sites and spoke with the staff who were involved, to discuss the reasons for the error and the actions they took in response.

We are also integrating with CQC's wider regulatory activities in enforcing the Health and Social Care Act. We provided specialist advice as part of CQC's hospital inspection programme on four occasions, based on factors including risk, availability of staff and the location of the service, and we advised on registering new providers using medical radiation on two occasions. CQC is developing a comprehensive inspection programme of radiology departments, and we contributed to the strategy for this work. To support this, and our IR(ME)R enforcement work, we have increased the number of inspectors in our team.

Our updated website provides information and guidance for providers and our notifications webform also now includes the latest organisation names in both the NHS and independent sectors.

To encourage consistency in reporting, we have supported joint professional bodies to develop proposals and guidance for making notifications of exposures 'much greater than intended' and have advised on categorising different types of error in radiology.

As well as this, we have contributed to the work of the Clinical Imaging Board, including publishing further guidance to organisations about making additional checks and assurances before initiating an exposure, to reinforce the Pause and Check initiative. We also supported the Radiotherapy Board to progress proposals for guidance about radiotherapy imaging errors/incidents, and the circumstances when these categories of error become notifiable under IR(ME)R. These boards were established across the three major professions involved in imaging and radiotherapy – the Royal College of Radiologists, the Society and College of Radiographers and the Institute of Physics and Engineering in Medicine.

We have presented our work at national conferences (the UK Radiotherapy and Oncology and the UK Radiological Conferences), at national 'IR(ME)R study days' and at other 'learning from incidents' meetings. Similarly, at meetings with partner enforcement authorities from across Europe, we have discussed approaches to justification and authorisation and learned from each other's respective approaches.

We also exchange information with other IR(ME)R enforcement authorities in the UK and other enforcement authorities 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 forum enables us all to share trends and discuss incidents.

CQC has been making a significant contribution to the consultation meetings run by the Department of Health for the transposition of the new Basic Safety Standard Directive 2013/059. This Directive has to be transposed into UK law by February 2018. These new regulations will bring new challenges as they will include non-medical imaging exposures (using medical radiological equipment). At the time of writing, unintended patient exposures due to equipment failure are also likely to fall within the remit of the forthcoming revised 'IR(ME)R' regulations.

Overall notifications of exposures 'much greater than intended' in 2015

Regulation 4(5) requires employers to notify CQC of exposures of ionising radiation that are much greater than intended, which are errors resulting from procedural failures rather than equipment malfunction. In 2015, we received a total of 1,277 notifications, which is an increase of 16% compared with 2014, when we received 1,103.

Of the 1,277 notifications:

- 1,027 (81% of the total) were from **diagnostic radiology** departments. Well over a third of these errors resulted in the 'wrong patient' undergoing a diagnostic imaging examination, a similar figure to 2014.
- 52 notifications were from **nuclear medicine** departments, which is a small decrease from the 55 received in 2014. In 2015, we received only two notifications of therapeutic nuclear medicine errors.
- 198 notifications were from **radiotherapy** departments. Of these cases, 130 were categorised as 'radiotherapy imaging', a higher proportion than in 2014. This left 68 notifications not related to imaging, which is broadly in line with previous years.

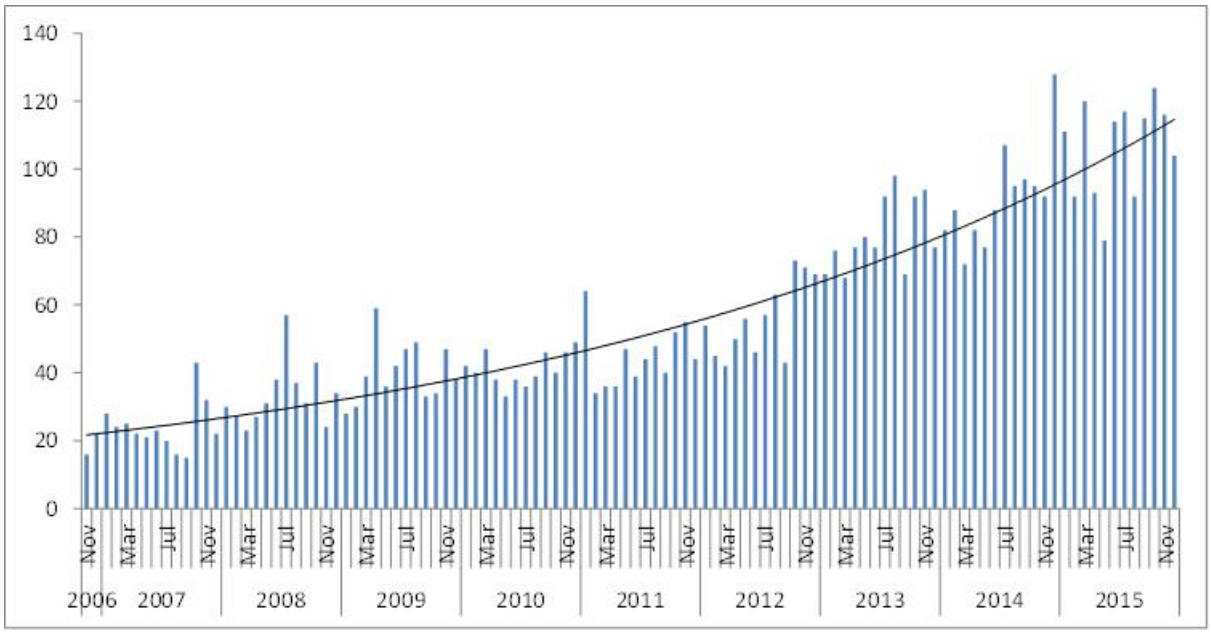
Figure 1 shows the annual number of notifications made to us. Since the responsibility for IR(ME)R enforcement in England was taken on by the Healthcare Commission at the end of 2006, there has been an overall 4.5-fold increase in the number of notifications, which we discuss throughout this report. This represents a 20% year-on-year increase since we began collecting this data.

For the first time, we present information describing the distribution of the 'source' of the notifications – whether from the NHS acute sector, independent or primary care providers. Figure 2 shows how the monthly rates have increased in England since November 2006.

Figure 1: Notifications received, 2006/7 to 2015

Organisation type	2006/7	2008	2009	2010	2011	2012	2013	2014	2015
NHS acute	317	379	457	460	514	638	918	1,060	1,210
Independent hospital	10	19	19	28	22	28	47	38	63
Other (inc primary medical & dental)	2	4	6	6	3	3	4	5	4
Total number notification	**329**	**402**	**482**	**494**	**539**	**669**	**969**	**1,103**	**1,277**
Percentage change		22.2%	19.9%	2.5%	9.1%	24.1%	44.8%	13.8%	15.8%

Figure 2: Monthly rates of notifications 2006/7 to 2015



This report includes details of the numbers of notifications in each of the modalities for a year-on-year reflection and comparison. The data reflects all the notifications that CQC received.

We acknowledge that there is a genuine variation in how providers interpret guidance from the Department of Health that requires them to notify to IR(ME)R enforcement authorities. To address this, we have contributed to the Department of Health's new guidance, which we hope will help to ensure more consistency in interpretation.

Over the last two years, there has been a year-on-year increase in the number of radiology notifications of approximately 15%. This should be seen in the context of an increase in acute radiology activity of about 5% each year over the same period, as well as an increase in NHS dental radiology of approximately 10% in 2014/15 compared with 2013/14. We believe the increase in the rate of notifications is a result of:

- changes in how providers interpret the guidance of what constitutes a reportable notification to CQC
- confidence in organisations in disclosing human errors to us, and working with us to raise awareness locally and in introducing measures to mitigate the chances of a repeat of that error.

We therefore have no reason to believe that practice is getting worse. Rather, we attribute the increase in notifications to an improvement in awareness of what needs to be notified to us, particularly as professions have been involved in developing new guidance, such as 'Pause and Check'.

We are aware of variations in the numbers of notifications reported by different organisations. Figure 3 shows a brief analysis of the numbers of notifications from NHS trusts, not taking into consideration their respective size or activity.

Figure 3: Notifications from NHS trusts in 2015

Number of notifications received in 2015 (all modalities)	0	1	2-4	5-9	10-19	>20
Number of NHS trusts reporting	15	15	46	35	29	14

It is possible that the results above might indicate either a variation in the reporting culture of trusts, or a variation in how trusts interpret the existing guidance of what is notifiable to us, which is currently being addressed by the Department of Health.

We have consistently regarded 'zero notifiable errors' in a year as being unlikely in a modern NHS acute trust. We have used this metric to help us prioritise trusts for an IR(ME)R proactive compliance inspection and have challenged the way in which organisations identify notifiable errors to ensure that staff are trained to identify them, feel confident in being able to do so, and that they then go on to disclose them to us. CQC's Hospitals directorate has signalled that we should report on this metric in future reports to identify those who have not made a notification to us.

Diagnostic radiology notifications

In 2015, we received 1,027 notifications following errors that led to patients receiving exposures much greater than intended in diagnostic radiology, which, like most previous years, comprises around four fifths of the total numbers of notifications across all modalities. Figure 4 provides a breakdown of the source of errors made in radiology exposure.

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 5% overall (and by over 10% for CT).[a]

The report from NHS England shows that there are around 40 million imaging tests overall in the NHS acute sector, comprising some 22.6 million x-rays, 4.2 million CT scans and over 1 million fluoroscopy examinations, but with more in the NHS dental sector (over 14 million) and more still across the independent health care sector. There is no publicly available central reporting structure for numbers of exposures taken in the independent sector.

Figure 4: Notifications from radiology, since 2006/7

Organisation type	2006/7	2008	2009	2010	2011	2012	2013	2014	2015
NHS acute	229	292	374	380	424	535	736	867	975
Independent hospital	9	17	19	24	18	25	42	28	48
Other	2	3	6	6	3	3	4	5	4
Total number notifications	240	312	399	410	445	563	782	900	1,027

It is worth drawing attention to a potential anomaly in the ratio of the number of x-rays compared with CT scans reported by NHS England (22 million x-rays and 4.2 million CT scans), which does not reflect the respective ratio of the number of notifications that we receive (figure 5). To some extent, this may be explained by the difference in multiplying factors in existing guidance. We expect the new guidance to clarify notification requirements from radiology departments, but we wish to reinforce that IR(ME)R notifications apply to **all** medical exposures, irrespective of the size of the dose and whether they are 2D projection radiography or CT scans.

However, the proportion of radiology notifications of errors involving CT scans has remained steady over the last three years (figure 6). This is alongside the increase in activity within the same period, as reported by NHS England.

a. https://www.england.nhs.uk/statistics/wp-content/uploads/sites/2/2014/11/Annual-Statistical-Release-2014-15-DID-PDF-1.1MB.pdf

Figure 5: Submodality of diagnostic radiology notifications in 2015

Type of notification	Number of notifications
CT	571
Radiology using film/CR/DR	400
Mammography	17
Dental	14
General fluoroscopy	14
Cardiac	4
Interventional radiology	4
DXA	3
Total	**1,027**

Figure 6: Percentage of notifications of CT scans as a proportion of those from radiology

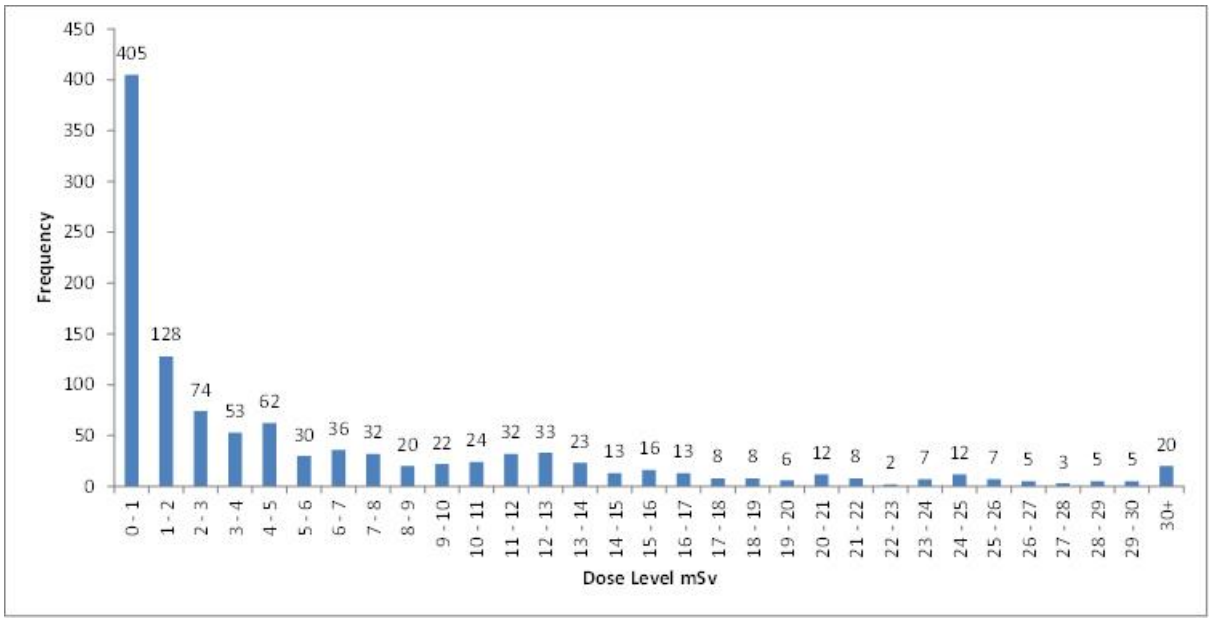
2006/07	2008	2009	2010	2011	2012	2013	2014	2015
17%	33%	43%	43%	42%	48%	56%	57%	56%

Figure 7: Analysis of errors in radiology departments (notifications in 2015)

Type of error	Number of notifications	% of total
Referrer error – wrong patient	243	69.6%
Referrer error – no check back	61	17.5%
Referrer error – wrong anatomy or modality	28	8%
Timing error for examination/booking	15	4.3%
Referrer error – other	2	0.6%
Total referrer errors	**349**	**34%**
Operator error – wrong anatomy/laterality	221	32.6%
Operator error wrong exposure set	161	23.8%
Operator error – failure to ID patient	97	14.3%
Operator error – modality selection	45	6.6%
Timing error for examination/booking/NGT timing	44	6.5%
Operator error – no check back of previous	43	6.3%
Operator error – image archive/labelling	34	5%
Operator error – other	33	4.9%
Total operator errors	**678**	**66%**
Total diagnostic radiology notifications	**1,027**	

Figure 8 shows the frequency of reported doses that patients received for errors in diagnostic radiology exposures in 2015. 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 (36.4%) of all our notifications in radiology result in an effective dose of 0-1mSv, and only a very small proportion of our notifications (1.8%) deliver a dose of 30mSv or greater.

Figure 8: Distribution of patient doses from radiology notifications in 2015



We are not aware of any difference in the type of error and the size of the dose estimate notified to us, and there is no reason why they should be different. In future, we will be clear that the dose value that should be notified to us should represent the dose delivered in error (as we have indicated on our notification website). Some trusts occasionally fill in the dose field when notifying us about radiotherapy imaging errors. For 'high-dose' radiology notifications we will focus on the organisation's response to ensure that it guards against a repeat and shares learning with colleagues to protect subsequent patients from such exposures.

More information on radiation doses to patients is available on the Public Health England (GOV.uk) website. However, it might be helpful to explain here that the vast majority of 2D projection radiographs such as chest, abdomen and skeletal x-rays will fall into the first category (0-1mSv) and that CT scans of the head, chest and whole spine would deliver approximately 1.4mSv, 6.6mSv and 10mSv respectively. These dose levels compare with the UK average annual radiation dose of 2.7mSv.

Key findings from notifications and inspections in radiology

The following are some key themes from our work in radiology in 2015, which we hope will help providers to improve their own compliance locally.

Radiographers must read the whole referral. Key parts of request forms are sometimes omitted or only partially read. Sometimes, operators rely on information on radiology information systems (RIS) to help determine which examination to undertake, or they rely on what the patient themselves told them, rather than reading the whole referral, resulting in an inappropriate examination. We have also noted errors arising from using hand-written worklists and using whiteboards.

Some referrers fail to cancel unnecessary or incorrect referrals in a timely way or they didn't know how to cancel an examination properly because the correct process wasn't communicated as part of their induction training from the radiology department. Or, they simply had not followed the established process (which often requires the examination to be cancelled electronically as well as telephoning radiology reception).

There is still confusion around the basis for authorising exposures – whether staff are acting as IR(ME)R practitioners in their own right, or authorising under guidelines issued by an overarching IR(ME)R practitioner, often the radiology clinical director. We ask that those responsible for this local decision review and clarify this, and to make sure that staff are aware, and that they are adequately trained to undertake these tasks.

Numerous operator errors involve use of equipment. These include selecting the wrong detector or wrong automatic exposure control device, or that a detector was selected when a 'direct' exposure was required. We note that most modern equipment has been designed to protect against 'significant' over-exposure. We therefore suggest that organisations provide training and have standard operating procedures (SOPs) when their systems enable some functionality and controls to be overridden. Operators should understand the implications of overriding such controls and how to mitigate the degree of Automatic Exposure Control over-exposure if there was a fault condition.

'Pause and check' should remain active and shouldn't become assumed, disregarded or forgotten. We have consistently received positive feedback from colleagues about the impact of pause and check. Some organisations have chosen to adopt it into their employer's procedures, requiring staff to follow it as set out. This includes checks of previous imaging (whether as part of justification or as part of a pre-exposure checklist). Responsibilities should be clear.

A large proportion of errors originate from referring clinicians. While pause and check processes should highlight some of these errors, they were not designed to stop all errors made by referrers. We are increasingly asking organisations that notify such errors to us about their local initiatives to guard against repeat referrer errors and how they disseminate learning across the organisation. Although a one-to-one discussion with the individual is helpful and will likely prevent them personally making the same mistake again, we often look for wider organisational learning to be shared across the directorate or trust, including efforts within radiology to detect referrer errors. We have asked organisations to consider introducing a reminder for referrers to check that they have selected the 'right patient, right test, right time'.

The quality of training records varies. We occasionally see how some categories of staff have few, if any, training records, including agency/locum radiographers. We expect organisations to keep and provide training records as evidence that staff can operate equipment safely and that they provide adequate assurances for agency staff training in accordance with Regulation 11(5). The same requirement for operator training applies to radiologists and others, such as cardiologists and orthopaedic and vascular surgeons, who operate x-ray (including interventional imaging) equipment themselves. Our work in this area has extended to serving formal enforcement notices, which are published on our website.

Key findings from inspecting radiology services in comprehensive inspections

We have seen greater learning from incidents and complaints – including human factors training, more audits, and improvement in local governance arrangements.

More radiology departments are seeking to achieve national accreditation[b], and are working to resource project teams to undertake a gap analysis for their department and move towards full accreditation.

Radiology departments have responded well to meeting two-week waits and associated diagnostic targets. Since the drive to cut waiting times, the work of radiology departments appears to have a greater visible presence, which has resulted in departments working more with senior management and improved radiology governance. But alongside this, the number of unreported images has increased and departments have struggled to achieve satisfactory turnaround times of reports, especially for more complex imaging in CT and MRI.

There has been a year-on-year increase in the demand for radiology services nationally, with little or no associated increase in resources (staffing and equipment). We are aware of a national shortage in many staff groups, particularly sonographers, clinical scientists and both paediatric and breast radiologists in district general hospitals. We continue to see outsourcing of imaging services (predominantly MRI) and reporting – either by internal consortia or through reporting agencies – to meet the growing demands on services.

More non-radiology staff are operating x-ray equipment without always having the associated training or records and audit arrangements in place.

We are aware of issues associated with re-procurement of picture archiving and communication systems (PACS) and radiology information systems (RIS). These include issues with data migration with associated data loss; gaps in reporting after migration; the cost of migration for some, with some companies charging large fees to release data; and training implications of new systems for all staff groups. However, on the plus side, local hospitals are increasingly communicating with each other and sharing good practice and issues that they find.

b. https://www.isas-uk.org/default.shtml

Nuclear medicine

In 2015, we received 52 notifications from nuclear medicine departments, which is comparable with previous years. Table 6 shows how the number of notifications has changed since we began collecting this information. Figure 9 also shows the source of the notification (either NHS or independent sector) since 2006/07.

The categories of error in 2015 were comparable with previous years in terms of 'referrer' and 'operator/administration' errors.

Figure 9: Nuclear medicine notifications 2006/7 to 2015

Organisation type	2006/07	2008	2009	2010	2011	2012	2013	2014	2015
NHS acute	22	29	32	25	24	38	46	48	47
Independent hospital/other	1	3	0	1	1	1	4	7	5
Total number notifications	**23**	**32**	**32**	**26**	**25**	**39**	**50**	**55**	**52**

Although not shown above, the breakdown between diagnostic and therapy nuclear medicine exposures was again typical, and in 2015 we received just two notifications arising from radionuclide therapy.

Key findings from notifications and inspections in nuclear medicine

Notifications relating to incidents in radionuclide therapy are potentially serious. Errors in treatment exposures always come under much closer scrutiny, reflecting the additional doses and risks, and often result in an inspection to enable us to meet with those involved and agree an action plan directly with the trust's management.

To share some of the learning from notifications with nuclear medicine professionals, we summarise the notifications received in 2015 below, separated by the type of exposure.

Radionuclide therapy

We received two notifications of this type; the first related to the use of iodine-131 (I-131) to treat thyrotoxicosis with 600MBq administered rather than the prescribed 400MBq. Learning included strengthened procedures, improved patient-specific capsule labelling and independent checking and record keeping. The second incident concerned radium-223, used to treat skeletal metastases for a patient with prostate cancer. The error in one of six fractions arose from a

miscalculation in the patient weight-dependent activity to be administered, resulting in approximately 30% less activity/dose given than was prescribed. This under-dose was accepted as a voluntary notification.

Diagnostic nuclear medicine

We received 50 notifications of this type of error, which are divided equally between those from referral and those that occurred within the nuclear medicine department. The latter were mainly mistakes by the operator and some 'system' errors including non-IR(ME)R duty holder staff occasionally at fault. The diagnostic notifications are summarised below.

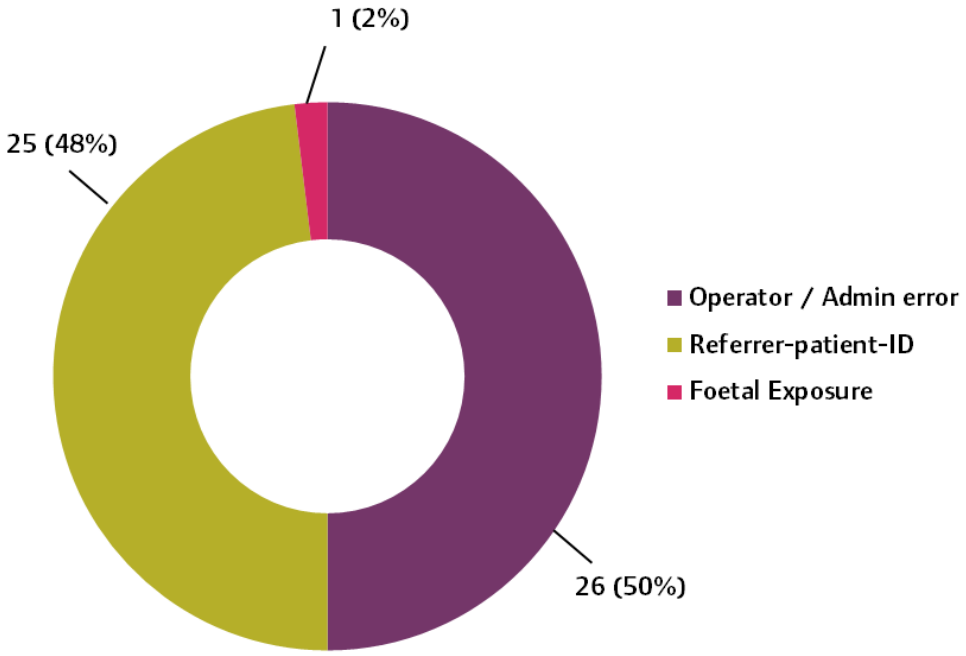
Unintended exposure of patients due to patient identity errors by the referrer: Erroneous requests for nuclear medicine scans comprise approximately a quarter of the total notifications received over 2015. As with other modalities, the learning is common, such as the introduction of a 'pause and check' list. We have also seen that providers have considered introducing software 'prompts' at the point of referral. We acknowledge there may be little in the clinical detail to alert the ARSAC-holder or nuclear medicine radiographer authorising the request to such referrer errors. However, the 15 or so instances in nuclear medicine is very small compared to the number of nuclear medicine investigations performed annually. That said, unnecessary investigations do include PET CT, which are relatively high dose.

Repeat requests and failed cancellations between the referrer and nuclear medicine department: These combine to produce the next most common type of error, followed by a few cases where referrers selected the intended patient but the wrong scan, test or modality. Staff need to be trained on the requesting system, and as the number of common nuclear medicine examinations is relatively few, there should be little difficulty in making these explicit within the system. We note that 'paper' nuclear medicine requests are often colour-coded to help distinguish the intended modality of the request.

Intended cancellations of nuclear medicine requests may fail for a variety of reasons, whether because of unfortunate timing or failed communication. The cancellation process must be clear to the referrer and generally will require a direct phone call to the nuclear medicine department as early as possible.

In our previous reports, we have drawn attention to a significant number of notifications where nuclear medicine bone scans were performed in error when the referrer actually meant the patient to receive a DXA or other type of bone scan. We received only one such notification over 2015, which suggests that this risk is now more widely recognised and controlled, and referrers are more aware.

Figure 10: Type of error (nuclear medicine 2015)



Notifications arising from mistakes in radioactive medicinal product (RMP) administration: These errors were generally made by the nuclear medicine operator, and accounted for over half the notifications in 2015. Safe laboratory practice is key to ensuring that the RMP vial or syringe is correctly labelled, stored, checked and available for administration, thereby reducing the risk of staff picking up the wrong RMP. The final patient identity check in nuclear medicine as enshrined in the employer's procedures must always be 'three-way': patient identity v request v RMP about to be administered to the patient.

In a few instances, the correct RMP was administered, but with more than the intended radioactivity. These were generally low risk and within the tolerance set down by ARSAC guidance and also may not have exceeded the criteria to be classed as 'much greater than intended'.

Notifications involving PET CT exposure: Over 2015, approximately 20% of nuclear medicine notifications were from this modality. These often also constitute the relatively high dose incidents in diagnostic nuclear medicine. The maximum effective dose quoted over 2015 was 44.5 mSv, which related to an incident where scans on three patients were performed with an incorrect protocol, including repeats. PET CT apparatus is relatively complex, particularly in terms of control software around image registration, reconstruction and archival. This can occasionally pose challenges for operators. Training is crucial and competency needs to include familiarity with all aspects of operation, not just the features used daily.

In summary, and despite the findings above, the number of notifications is still very small in comparison with the number of successful nuclear medicine exposures performed annually. The fact that nuclear medicine is subject to safe laboratory practice and a strong regulatory framework in addition to IR(ME)R is important.

Radiotherapy

Figure 11 shows how the numbers of notifications from radiotherapy departments in NHS and independent hospitals has changed since the start of this data collection in 2006/07.

Figure 11: Radiotherapy notifications 2006/07 to 2015

Organisation type	2006/07	2008	2009	2010	2011	2012	2013	2014	2015
NHS acute	66	58	51	55	66	65	136	145	188
Independent hospital				3	3	2	1	3	10
Total number notifications	**66**	**58**	**51**	**58**	**69**	**67**	**137 (73)**	**148 (76)**	**198 (130)**

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

The numbers of treatment errors notified to us has remained largely consistent over the past four years at around 70 each year. However, the number of notifications arising from radiotherapy planning and verification imaging errors in 2015 increased by over 70% from 2013/14. This is likely to be indicative of a greater awareness to notify these errors, compounded by a significant variation in practice cross the radiotherapy community. We are confident that the anticipated new guidance on errors involving radiotherapy imaging exposures will lead to a more consistent approach between radiotherapy centres in the future.

Data courtesy of the National Cancer Services Analysis Team shows that activity as measured in terms of radiotherapy attendances (a surrogate for fractions) has fallen very slightly by only 1% in the last year. This is principally as a result of implementing new dose/fractionation protocols in treating breast and prostate cancer.

Figure 12: Sub-modality of notifications (radiotherapy 2015)

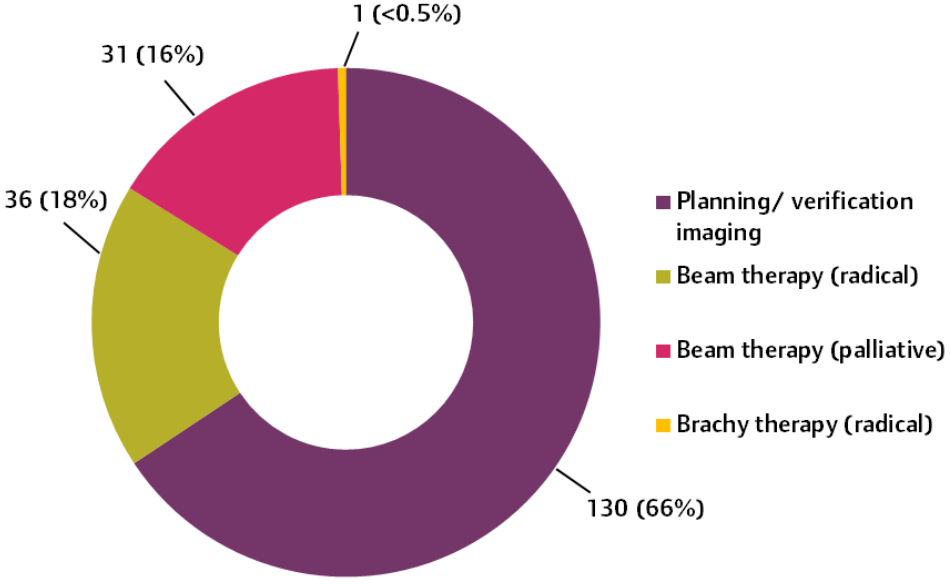
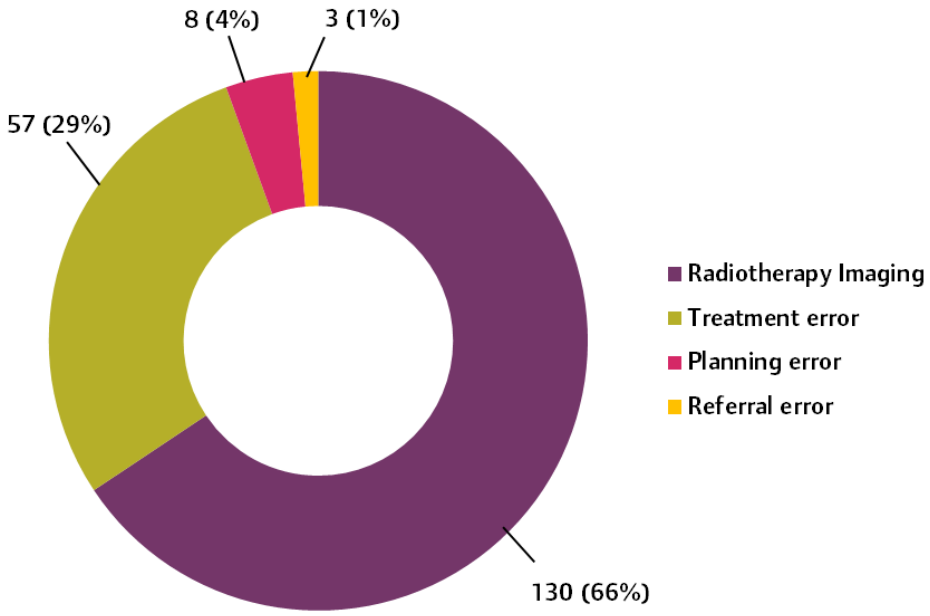


Figure 13: Type of error (radiotherapy 2015)



Key findings from notifications and inspections in radiotherapy

To share some of the learning from notifications, we have summarised the notifications received during 2015, separated by the type of exposure. We hope these 'high-level' findings from our work in radiotherapy will be helpful to departments as they strive towards safer radiotherapy – in this case, through IR(ME)R regulation and notifications.

Repeat planning and verification exposures

Over 2015, we received 130 notifications involving radiotherapy planning and verification exposures, which is a 70% increase. We believe this is a result of greater awareness of the Department of Health's 2012 guidance for diagnostic exposures, in which repeat 'high dose' exposures due to procedural failure became subject to notification as being much greater than intended.

Notifications of incidents of repeat planning CT scans involved failures to cover the required anatomy because of lack of clarity or misreading the request, selecting the wrong protocol, failing to attach markers or position the patient appropriately or with incorrect accessories/immobilisation. Other 'system' errors included the 'timing' of scan or failed cancellation when patient management deviated from planned treatment.

In radiotherapy verification, repeat imaging often followed difficulty in 'online' matching of anatomy or a missed shift of some kind, which needed an adjustment of the patient, field or markers and a repeat verification scan to confirm that the patient is correctly positioned. We have highlighted previously that in this situation, where the imaging highlights a geographical

miss that has the potential to go through to the treatment and then confirms satisfactory correction, then it is actually 'doing its job'. In forthcoming revised guidance, we anticipate that the majority of such events will no longer be classed as 'much greater than intended'. Other verification imaging incidents include imaging additional to local protocol, the wrong type of image, operator unfamiliarity with device or software and difficulties in image construction/handling or demographics.

Treatment errors

We received 68 notifications over 2015 relating to errors in treatment. Approximately two thirds related to geographical miss of the planned treatment volume, the rest related to an overexposure of the target compared to the dose prescribed. The numbers of treatment notifications have remained largely consistent over recent years.

Geographic misses: These generally occur for one fraction only and often the prescribed dose to target can be corrected over the remaining course. There is a lack of specific regulatory or professional guidance on what degree of 'miss' constitutes 'much greater than intended', and we have seen variation in practice across centres in England on whether these should be notified to us. With ongoing developments in radiotherapy technique and in anticipation of revised patient protection legislation in 2018, early review of current practice by relevant professions would be worthwhile.

Treatment notifications generally comprise set-up errors by treatment staff, such as incorrect moves from reference marks, using the wrong tattoo, failure to return the couch to its predetermined position, or errors in matching of anatomy, for example selecting the wrong vertebrae during verification. Online matching appears to be more prone to errors than offline review and departments should involve a third pair of experienced eyes where necessary if there is any doubt.

Occasionally, geographical misses originate before treatment set-up or delivery. For example, incorrect reference marks may have been applied at the planning stage or mistakes in set-up instructions, or with multiple phase treatment errors in changing isocentre. Such errors will go through to treatment if not picked up in planning, pre-treatment or first day checks.

These checks are most likely to be ineffective where the root cause of the geographical miss lies in an error made by the practitioner or planner at the beginning of the pathway. For example, the wrong anatomy or scar marked up for treatment, the incorrect target volume outlined on the planning scan, or a basic laterality error of some kind where the wrong side is marked for treatment. With potential for such errors to remain undetected over the course of treatment, they tend to be high risk and may have significant clinical impact. Departments should aim to ensure that independent checks are made throughout the pathway and that there is a multidisciplinary culture where practitioners and operators can challenge each other without blame to highlight mistakes or to present this differently to jointly "make a good catch".[c]

We have previously drawn attention to geographical misses in skin treatment. Irrespective of whether this is x-ray or electrons, treatment is not always delivered to the correct site. When it

c. Robert D Adam, University of North Carolina, *Engineering continuous quality improvement program in a radiation oncology department: A journey towards high reliability, validity and safety mindfulness*, UKRO 2016, SCoR/ASRT international exchange.

fails, learning is usually apparent around the need for a strengthened process on accurate target definition/delineation, whether the failure is due to a lack of clarity from external referral, or by the clinical oncologist in marking up the patient. Lasting skin markings, appropriate skin coverage and good quality photographs in clinic, clearly labelled templates, accurate diagrams and reference to clear anatomical markings, can all be important depending on the site and complexity of skin blemishes present.

Direct 'overexposure' during treatment: These notifications were much less common than geographical misses. This could perhaps reflect that the 10%/20% criteria for 'much greater than intended' are clear and well established. However, a few were 'voluntary' notifications, where the error in delivered dose was less than the multiplying factor or was actually an 'under-dose' compared to that prescribed to the treatment volume. One such unusual voluntary notification involved several patients. Routine quality assurance checks showed that during commissioning of the accelerator some time previously, an error had arisen in the calibration of an electron applicator.

Elsewhere, the most common sources of treatment overexposure arose from calculation errors in planning/pre-treatment, or in treatment delivery where a shorter focal skin distance was inadvertently used, usually from a failure to return the couch to its intended position or by using the isocentre from a different phase of treatment.

Although 'much greater than intended' multiplying factors are specific numerically, we received a few notifications of incidents not because the target was overdosed, but doses to organs at risk were significantly above that intended. These were a result of mistakes in provision of shielding or unforeseen patient position, whether in planning or in treatment delivery. Again, the method of calculation is important in determining whether the error was notifiable or not, and professional guidance would be helpful.

The need for a patient identity check procedure in IR(ME)R compliance is well understood, but each year we receive two or three notifications involving a patient being treated using another patient's plan. Fortunately such incidents, arising from patient queue complications and/or lack of communication between staff, are usually quickly realised and treatment is confined to a single fraction or field. It is worth reiterating that the final identity procedure in treatment must always be against patient demographics, treatment sheet/plan and patient selected on computer console, including any checks in the room, and these should be reflected in procedure.

In all types of radiotherapy notifications, a traditional 'sense' check by the operator, for example reviewing the anatomy or checking the applied field or light beam on the patient could have highlighted the error. Radiology colleagues are now firmly wedded to a 'pause and check' culture, and this type of check and monitor can prove worthwhile in some departments that use increasingly sophisticated radiotherapy technology, hardware and software.

At the time of writing, we are aware that Public Health England is enhancing learning, through its Patient Safety in Radiotherapy Steering Group, by:

- refining the radiotherapy pathway coding to reflect contemporary radiotherapy practice
- introducing safety barrier coding to identify effective methods to detect errors
- proposing a causative factor taxonomy.

Meanwhile, the Society and College of Radiographers is developing 'pause and check' guidance from a radiotherapy perspective, following earlier work in radiology, MRI and ultrasound.

It is worth reflecting that some of the more serious incidents notified to us over recent years that had a clinical impact on the patient, or had the potential to do so, arose when treatment was unintended or unnecessary and was delivered by mistake.

Examples include where radiotherapy is originally prescribed, but when patient management changes, messages are not communicated and treatment is not cancelled. Another example is where a patient with a diagnosis of cancer has an 'external' referral into radiotherapy, but the diagnosis is found to be wrong, and again, the error is not communicated, or treatment has already been delivered.

What typifies such incidents, and which can present difficulties for CQC's remit under the regulations, is that the root cause will sometimes be prior to the IR(ME)R pathway. Individual radiotherapy IR(ME)R duty holders are therefore unlikely to be involved at this stage. Instead, the focus will be on decisions of other clinicians or actions arising from multi-disciplinary teams, sometimes from a separate trust. This type of 'medical' error may be occasionally inevitable, and the relevant aspect that CQC can investigate within the radiotherapy context is the 'referral criteria' required under IR(ME)R. In developing treatment protocols and referral criteria for radiotherapy treatment, it is important that the tumour type and site specific minimum criteria are clearly laid down and include indications for treatment and contra-indications for entry into the pathway.

Work in 2016 and beyond

Strengthening our inspection work

We have recruited and trained two additional IR(ME)R clinical specialist inspectors to our team. Each will have responsibilities for IR(ME)R enforcement in radiology across specific regions, and for supporting our wider comprehensive hospital inspection programme. We now hope that we will be able to adopt a better balance of compliance inspections and investigations of notifications.

Our work in 2016 will include:

- Work with stakeholders at Public Health England and the Department of Health to prepare for the implementation of new regulations developed as a result of the Basic Safety Standards Directive.
- More IR(ME)R inspections in radiology, nuclear medicine and radiotherapy. In radiotherapy, we will make IR(ME)R enquiries in relation to satellite centres and those in the independent sector in relation to the introduction of newer technologies, including intra-operative brachytherapy services. We will also ensure that the findings and recommendations from the 2016 Scottish investigation report are understood, reviewed and actioned where appropriate.
- Supporting professional education at conferences and study days.
- Continuing to support the Society and College of Radiographers in error coding, which will include a pilot of the recommendations of the working party.
- A small number of IR(ME)R radiology inspections, followed by further refining and amending our methodology to shape future IR(ME)R inspections.
- Establishing priorities for a new IR(ME)R radiology inspection programme across NHS and independent acute and primary care sectors, and committing to providing a 'themed' summary report, including overall findings to aid wider understanding.
- Establishing a dialogue with radiation professionals in relation to the 'duty of candour' where patients are involved in errors involving medical exposures.
- Re-establishing a standard analytical tool to enable a comparison of trust-specific notification rates with national IR(ME)R data using activity data from the Diagnostic Imaging Dataset provided by NHS England.

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