

IR(ME)R annual report 2013

July 2014

The Care Quality Commission

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

Our purpose:

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

Our role:

We monitor, inspect and regulate services to make sure they meet fundamental standards of quality and safety and we publish what we find, including performance ratings to help people choose care.

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Summary

The Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) were established in 2000 to satisfy European Council Directive 97/43/EURATOM to ensure that all medical exposures in diagnosis, treatment, research and screening are individually justified and optimised. They were amended in 2006 and again in 2011. The EU Basic Safety Standards Directive set out to update, harmonise and replace a number of radiation protection regulations and was adopted in December of 2013. Regulators anticipate that new regulations for safeguarding patients and others from radiation, which will replace IR(ME)R, will be enacted during February 2018.

This is the seventh annual report on regulatory activities in England in enforcing IR(ME)R. The Care Quality Commission (CQC) enforces IR(ME)R in a number of ways. We enforce the regulations by inspection. Inspections can be a response to notifications of exposures 'much greater than intended' (MGTI), where we believe the circumstances described in the error require us to take a close look at local arrangements. We may also inspect to investigate allegations from whistleblowers, to proactively monitor or test compliance with IR(ME)R, or to support colleagues inspecting hospitals and primary care organisations under the Health and Social Care Act regulations if they have concerns in relation to the use of radiation. There were a number of inspections during 2013, some of them leading to enforcement action.

We also investigate errors made involving medical radiation, which healthcare organisations notify to us. Under Regulation 4(5), healthcare service providers in England that use radiation are required to notify us whenever there has been an exposure to patients judged to be much greater than intended. We investigate each notification made to us individually to a conclusion, once we are satisfied that the organisation has investigated the error satisfactorily, considered the risks to patients involved, and has considered or put in place measures to prevent a recurrence.

Errors will always happen in healthcare organisations. We believe that notifying such exposures to us is essential so that organisations accept their part in the error and learn from it, which mitigates the risks of repeat errors involving subsequent patients, thereby improving safety overall. The Department of Health's guidance on the criteria for notification changed in 2012, which has meant the number of notifications has risen markedly this year. This work created a significant challenge to us over 2013, but we believe the findings overall are an excellent illustration of transparent reporting that can lead to learning and improvement through regulation. In section 2 of the report we provide an analysis of the notifications for each modality and conclude by summarising the ongoing actions for ourselves and service providers in light of the report's findings.

Impact on patients

In each case we investigate, we take account of the radiation dose and risks to patients who were directly involved in the incident and consider whether there are wider implications that have the potential to impact on others. The quantitative dose and risk estimates, as recommended by the International Commission on Radiological Protection, are well

established. In 'diagnostic' medical exposures the threshold for 'deterministic' effects, such as loss of hair, cataracts and sterility, is very rarely reached, although some patients undergoing complex and lengthy procedures can receive high skin doses leading to burns as a result. The principal 'stochastic' risk (that is, relating to the probability of the event happening) from medical exposure is that of radiation-induced cancer, where it is believed there is no threshold and even the relatively low doses, as received in diagnostic examinations, carry some risk. The risks from therapeutic levels of radiation, whether in radiotherapy or nuclear medicine treatment, by their very nature, have more serious consequences if things go wrong.

For patients, ionising radiation tends to be an emotive and not well understood subject. We do not underestimate the psychological impact and anxiety on patients and their relatives when there has been a failure in their diagnostic or therapy procedure leading to an 'unintended' dose or 'overdose' of radiation. Patients and others are unlikely to be able to put the additional risk into context without support from those trained to do so in the hospital. The Department of Health's guidance since 2000 is that patients should be informed unless it is decided that it is in their best interests not to do so and instead an appropriate entry is made in their records. We are aware of work and debate within the professions on 'duty of candour' and when it may be in the patient's best interest for them not to be informed. This may be included within forthcoming guidance for professionals.

Notifications in 2013

In this annual report we provide a detailed analysis of notifications reported to us and subsequent learning. 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 received a total of 968 notifications in 2013, reflecting a significant increase of nearly 45% compared with 2012. We attribute this mainly to changes to the Department of Health's guidance on what constitutes a notification of exposure 'much greater than intended'. The amended guidance was published in September 2012. The principle change was to reduce the multiplying factor for 'high-dose' examinations from x3 to x1.5. We are now seeing the full impact of this in this first complete reporting year since that date.

Of these 968 notifications, 781 (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. However, using established radiation risk factors and excluding any social or psychological detriment, the impact on the patients involved in the majority of cases is judged to be relatively small. There can be exceptions, and computed tomography (CT) is at the upper end of the range of radiation doses in diagnostic x-ray. The risks arising from 'over-exposures' depend on the age of the patient, therefore such errors carry more risk when children (or foetuses) are involved.

We received 49 notifications from **nuclear medicine** departments, which is an increase from the 39 received in 2012. Risks here are generally similar to those in diagnostic radiology, but there is the potential for significant clinical impact when incidents occur during thyroid ablation or other nuclear medicine therapy treatments. We were pleased to note there were no such therapy notifications received during 2013.

We also received 138 notifications from **radiotherapy** departments. We categorised 72 of these as 'radiotherapy imaging', a new category that we introduced part-way through 2013. We amended our records retrospectively to account for this category for the whole year. Relative to the risks from errors that occur during the actual treatment exposure, dose arising from planning or 'verification' imaging, generally carries a very low risk.

Of these notifications, the 66 notifications that related to treatment constitute the highest risk category, both in terms of impact on the safety/effectiveness of the treatment and on the mental state of what is likely an already anxious patient. Risks vary from case to case and arise when, for example, the planned treatment volume may be overexposed, or more commonly, when an error in patient or radiation beam positioning can lead to a 'geographical miss', so that critical organs or other tissues at risk may be irradiated to a higher level than planned. Fortunately, most incidents occur for only one fraction of treatment and in many mistreatments, the subsequent fractions can often be adjusted to 'correct' the overall dose received by the target volume.

In summary, the table below shows the annual number of notifications made to us. Since we (as the Healthcare Commission) became responsible for IR(ME)R enforcement responsibilities in England at the end of 2006, there has been an overall three-fold increase in the number of notifications. The reasons for the increase are discussed in the report.

Notifications received, 2006/07 to 2013

2006-07	2008	2009	2010	2011	2012	2013
329	403	483	494	538	669	968

1. Our work in 2013

IR(ME)R compliance inspections

In 2013, we completed a programme of proactive compliance inspections of radiology departments and published an update of our findings. Other reactive inspection work was in response to notifications from three radiotherapy departments that we judged to be of sufficient concern for us to want to take a closer look. This involved meeting with department managers and those involved in the incident, to better inform our enquiries. We outline more about this work on pages 20-21. As mentioned below, we also undertook a number of IR(ME)R reactive inspections in relation to concerns about service providers that registration and compliance colleagues brought to our notice. In total we carried out 12 inspection visits.

Specialist support for regulation under the Health and Social Care Act

Throughout most of 2013 we provided significant specialist support to CQC colleagues with compliance and registration responsibilities under the Act. We provided support and advice and in some cases, where we judged risks to be significant, joined them on-site as part of their visit or inspection. Inspections included independent hospitals, treatment centres, imaging centres and dental clinics. Findings were generally fed into compliance or registration reports but in some cases this work led to enforcement actions under IR(ME)R as reported below.

CQC's IR(ME)R enforcement activities

In 2013 we served one prohibition notice and two improvement notices under IR(ME)R. It is worth noting that all the enforcement actions this year were derived from our work in support of colleagues, and all three were served on dentists who were found, on inspection, to have demonstrated little or no awareness of, or compliance with IR(ME)R. This included having no IR(ME)R employer's procedures, no protocols or diagnostic reference levels in place, and, in one case, no evidence of continuous education and training in radiation protection. The prohibition notice was served on a dentist who was using a very old x-ray unit, which was not optimised for patient exposure and we considered to present a significant risk to patients.

For more information on this activity, please go to the [Enforcement](#) page on our website, where we have published a register of all our enforcement actions, such as improvement and prohibition notices.

Analytical support to healthcare organisations

With analytical support, we further developed arrangements for sharing data with NHS trusts. We have accumulated notification data for all NHS trusts in England and can make this available as part of a comparison with the 'national picture'. NHS organisations are required to submit returns to the Department of Health about the number of imaging and

radio-diagnostic examinations (known as KH-12). By using the notification rates in radiology for example, set alongside 'activity data' in the form of KH-12 returns, we can assess whether any appear to be 'outliers' in relation to notification rates for every 100,000 radiological examinations. We plan to continue to provide bespoke analyses to trusts on request, to help them compare local notification rates against the national (England) notification dataset, as our resources allow.

2. Notifications of exposures 'much greater than intended', Regulation 4(5)

Notifications in 2013

In 2013, we received a total of 968 notifications, reflecting a 45% increase in the rate of notifications since 2012, when we received 669.

NHS organisations are required to submit returns to the Department of Health about the number of imaging and radio-diagnostic examinations (known as KH12). The data shows that the NHS in England has undergone a mean annual year-on-year increase in overall radiological activity of 2.4%.

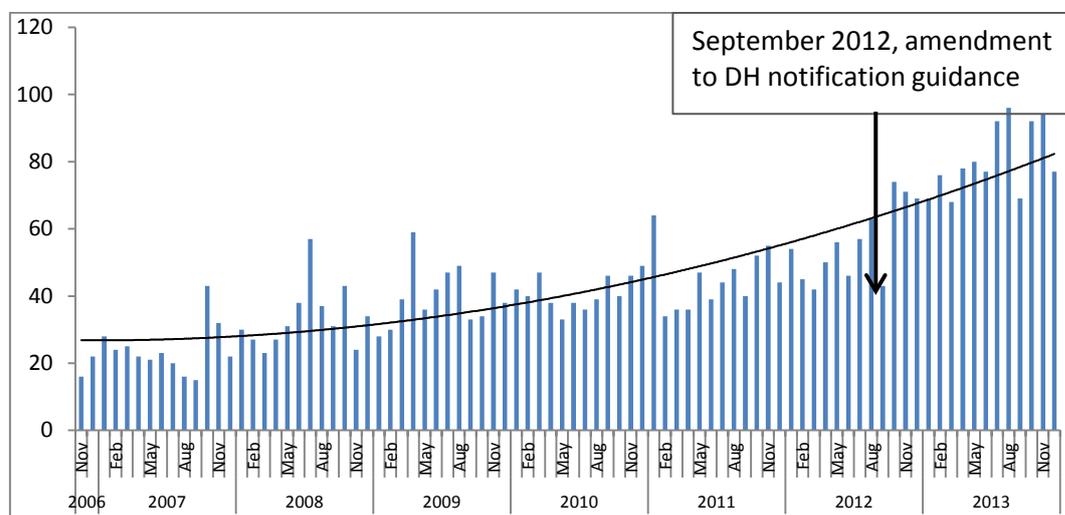
In previous years we judged that the overall numbers and rates (for every 100,000 imaging examinations) were low, at around one notification for every 85,000 exposures. Despite the increase in notifications arising from the change in guidance, we believe that the notification rates remain low overall.

Historically, we have taken account of 'weighted' notification rates across all NHS acute trusts, described above, to identify outliers, and to inform our priorities for inspection. We can take a similar approach to nuclear medicine imaging, and are able to use similar notification and activity data in radiotherapy using activity/attendance data.

Following the change in notification guidance in 2012, we expected to see an increase in notification rates from diagnostic radiology departments reporting 'repeat high-dose examinations' such as computed tomography (CT) scans. What was less expected was the impact of the new guidance on notification rates from radiotherapy departments arising from repeated planning and verification imaging exposures.

Figure 1 shows how the monthly rates have increased in England since November 2006.

Figure 1: Notifications received by month 2007-2013



Notifications in diagnostic radiology

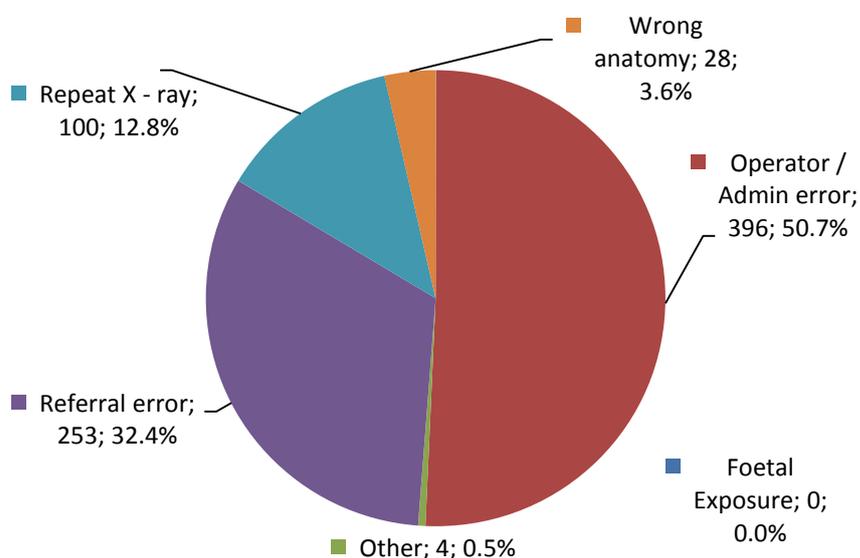
In 2013, we received 781 notifications following errors that led to patients receiving exposures much greater than intended in diagnostic radiology (figure 2). Overall, the numbers of notifications from radiology departments have increased year-on-year since 2006/7, when first the Healthcare Commission, then CQC, took over enforcement responsibilities of the IR(ME)R regulations in England. We believe that this increase reflects the confidence of departments in our enforcement methodology, which requires a demonstration of an effective internal governance process, a local investigation, development of recommendations and oversight to completion of an action plan to minimise the risk of a repeat error.

Notifications from radiology, 2006-07

2006-07	2008	2009	2010	2011	2012	2013
240	313	400	410	445	556	781

We acknowledge that it is not always straightforward to categorise the types of error consistently, and that the same error could be categorised in a number of different ways. Nevertheless, we hope it is helpful to provide broadly consistent data based on the best opinion of the inspector using the information provided in the initial notification.

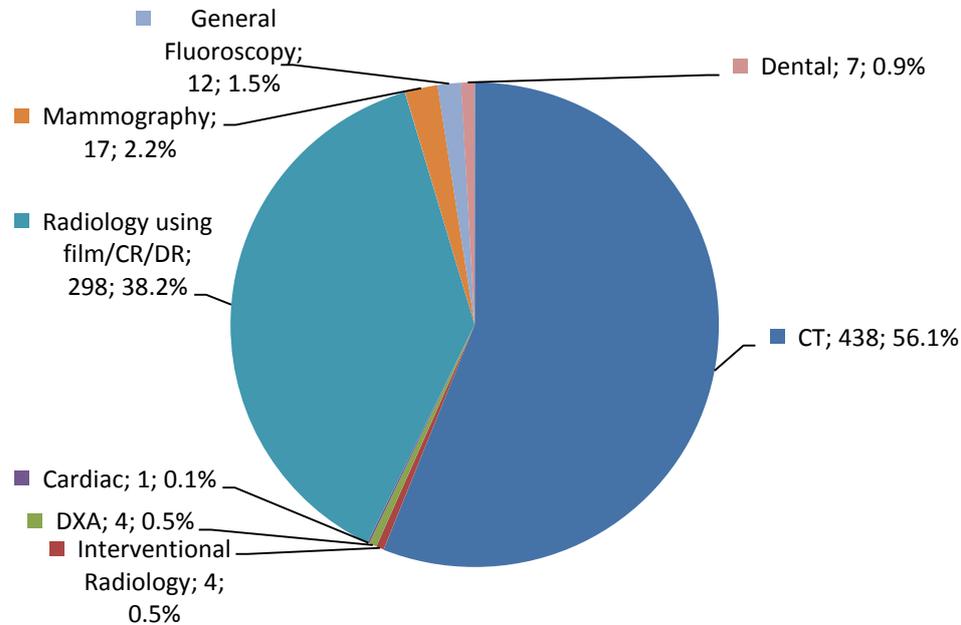
Figure 2: Type of error (diagnostic radiology 2013)



We carried out a separate analysis of all data from our radiology notifications – not just those restricted to 2013. This showed that the proportions in each category (‘all data’ and ‘2013 only’ data) were largely comparable.

Figure 3 shows the proportion and number of errors disclosed to us in 2013 in computed tomography (CT) and 'general' radiography (called 'film/CR/DR' in this report, i.e. computed /digital radiography respectively) alongside other x-ray submodalities where notifications were less common.

Figure 3: Submodality of notifications (diagnostic radiology 2013)



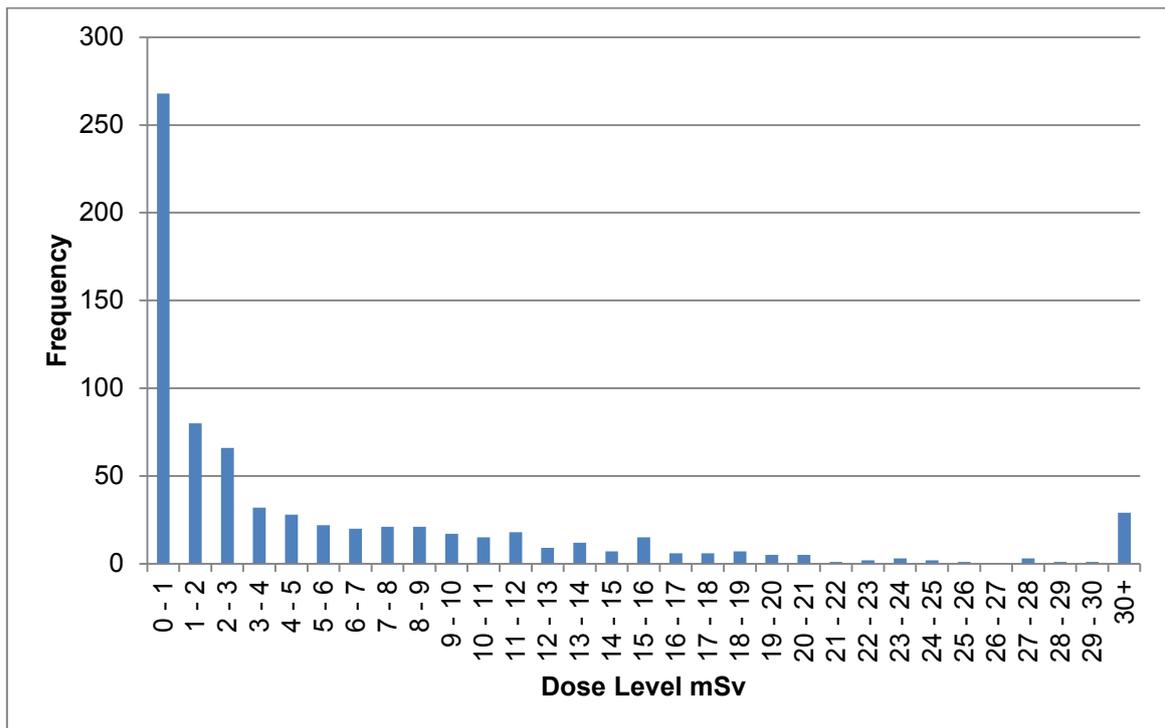
The table below shows the increasing proportion of notifications involving CT scans. The proportion of notifications involving errors made in CT scanning now comprises over half of all those received from the diagnostic radiology category. Again, we attribute this trend to the change to the Department of Health's guidance for MGTI, which requires providers to disclose repeat 'high-dose' exposures, including CT. We will continue to report this graphic, especially in the context of the changes to notification guidance already published, as well as any subsequent amendments.

Percentage of CT scan notifications:

2006-7	2008	2009	2010	2011	2012	2013
n/a	33%	43%	43%	42%	49%	56%

Figure 4 shows the frequency of reported doses given to patients involved in the 781 notifications of errors in diagnostic radiology exposures in 2013, where the dose was stated during the notifications process. Where it was not stated, inspectors estimated the dose where possible.

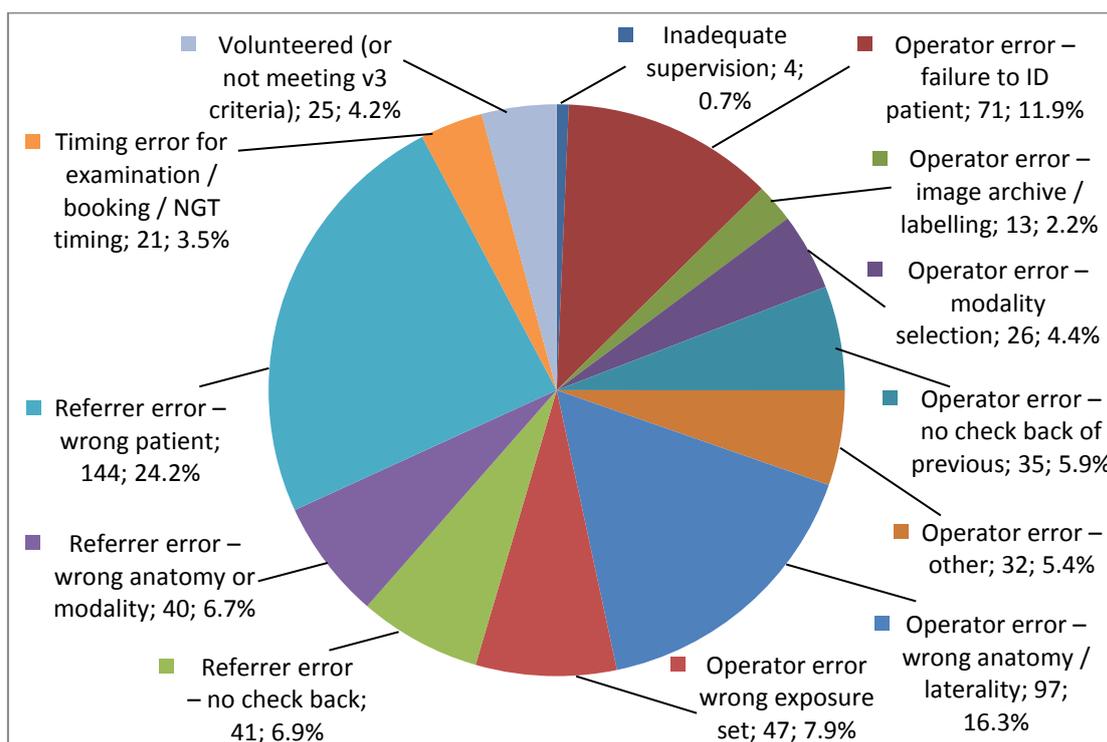
Figure 4: Distribution of patient doses from radiology notifications in 2013



We are aware that the approach in disclosing the dose value to us is inconsistent. Some departments have made notifications using the total dose to the patient arising, for example, from the intended as well as repeated examinations. We believe that the dose value reported should be that delivered **in error**.

As we investigate notifications of diagnostic radiology exposures and progress each one to closure, we take the opportunity to allocate a more accurate type of error than the simple categories shown in figures 2 and 3. Figure 5 on the next page provides a more detailed analysis of the 596 notifications that we closed in 2013 from radiology departments. It comprises a proportion of notifications received before and during 2013. It shows the proportion of 'operator errors' to be just over half at around 55%, and the proportion of the different 'referrer errors' at around 38%.

Figure 5: Analysis of errors in radiology departments (notifications closed in 2013)



We carried out a separate analysis of the detailed ‘type of error’ from **all** the notifications that have been closed. However, this separate analysis showed that the overall distribution of categories was largely comparable.

A review of errors in radiology

In previous reports we have consistently highlighted our concerns about errors involving the ‘wrong patient’ in diagnostic radiology. Although, for the first time, the proportion of such errors appears to now be a third of the total rather than a half, we understand that trusts feel this is an important failing whenever a referrer error or an operator error leads to the wrong patient undergoing an x-ray or scan intended for another patient.

At the start of 2014, we became aware of an allegation made against a radiographer who had been referred to their professional regulator, the Health and Care Professions Council (HCPC). The radiographer received a striking off order for:

- a) failing to properly identify the patient
- b) deleting the images from the modality workstation, and
- c) attempting to remove the evidence of the exposure from picture archive and communications systems (PACS) by involving colleagues.

Interestingly, the HCPC gave the view that “Failing to properly check whether (he) was carrying out a CT scan on the correct patient was a basic elementary failing which went far beyond mere lack of competence.” Details of the full hearing are on the HCPC [website](#).

We encourage all radiology staff to discuss the findings in risk meetings, to agree implications and a strategy to raise awareness of the importance of correct patient identification by radiographers and other operators. It goes without saying that staff should always be encouraged to disclose their errors to senior colleagues and management in accordance with local escalation policies.

Sharing good practice

In 2013, we began to share more widely the learning arising from one particular trust. This involved a number of 'operator errors' arising from failures of the patient identification (ID) checking procedures. This trust introduced an additional layer of checks for radiographers, which it called the 'pause' checks. It required them to check a patient's demographics (name, address, and date of birth), as is established practice in most organisations, as well as adding checks of clinical information, the site requested and checks of previous imaging, comprising a '6-point check'.

We were aware that some other organisations were reporting similar notifications. We therefore decided to share a modified version of the additional 'pause' checks with these hospitals to share good practice, and to encourage them to adopt the approach into their own IR(ME)R employer's procedures. These checks included: name, address, date of birth, site to be x-rayed, side, timing, modality, and whether it is justified (including an assessment of the clinical information provided, checks of previous imaging on hospital systems, and confirming with the patient themselves).

In some other cases we also suggested that the same or similar checks were equally valid to help referring clinicians before submitting a request.

After we shared the guidance, some NHS trusts decided to amend their local practice. We contacted some of these organisations for their feedback on the relative impact and success of using this initiative and provide some feedback below:

- Over the past seven years, one NHS trust has notified to us a large number of 'laterality errors' in skeletal examinations. Despite best local efforts and two IR(ME)R inspection visits from CQC, they continued to make these errors. We shared a modified version of the 'pause' checks described above. This prompted the local team to produce an in-house 'pause and check' poster to remind staff to check previous imaging, site and side – as well as patient demographics. We have since received noticeably fewer 'laterality' error notifications.
- The trust that originally developed the 'pause' guidance shared its own assessment of the difference made by using the check for three years. The number of notifiable incidents had reduced by 75%, with the main cause cited as duplication of requests made by referrers.
- Another trust adopted a modified World Health Organisation-Interventional Radiology checklist for operators to use before carrying out exposures in its 'time-out' checks. Again, this was successful in picking up errors as 'near-misses' – many being referrer errors in CT – as well as some 'justification' errors.

We shared this learning with the Society and College of Radiographers in 2013 and will be discussing with the radiation healthcare professions more widely in 2014.

More feedback from our work in radiology

Referral errors in light of electronic requesting

Although notification rates for misidentification of patients are low, they do still remain an issue within radiology – especially in light of the adoption nationally of electronic requesting packages. Feedback from trusts has highlighted that a lack of relevant training for referrers has been the main cause for the selection of incorrect patients. This can primarily be attributed to referrers searching for patients from ‘drop-down’ clinic or ward lists, rather than selection based on unique identifiers such as NHS or hospital numbers. But it can also be accounted for by the lack of vigilance by referrers during the submission process on checks of the request form made by the referrer, and the use of safety flags that question the referrer **“Is this the correct patient, modality and examination?”**

Proposed changes to notifications

We will discuss with professions involved in radiological protection whether there is a benefit in refining the guidance for radiology IR(ME)R notifications. For example, the patient doses and risks arising from ‘laterality errors’ in extremity and skeletal exposures are extremely small. Furthermore, the learning potential arising from operator errors is often easily managed through regular radiographer team meetings. We believe that these types of errors can be well managed within trusts’ risk and governance frameworks and they do not need to be disclosed externally to the IR(ME)R enforcement authorities. However, until the Department of Health recommends such guidance, we advise organisations not to amend their local practice.

We expect radiology departments to establish what checks are needed before they carry out an exposure, and ensure that these are reflected in local procedure. These would normally comprise checks made at the referral stage, and would possibly include automated checks made by the electronic requesting system (which can be set to flag inadvertent repeat examinations), and checks made within the radiology department using solutions within radiology information systems and picture archive and communications systems (RIS/PACS) as part of the justification process.

Automatic exposure control timers, detector selection and use of override keys

Another common theme in notifications in 2013 was incorrect detector selection and high back-up exposure settings, resulting in higher patient exposures. We received a number of notifications concerning digital x-ray units, which use an override key so that collimators can be manipulated for certain projections. The use of override keys can disable critical safety functions such as the automatic exposure control cut-off. We believe there is a trend here, including a lack of training on the safety features of x-ray units, insufficient supervision or processes surrounding the override key and, at times, a lack of awareness of how to use it correctly. We recommend that trusts work with manufacturers and application specialists, as well as medical physics teams to identify correct use and optimisation of back-up exposures should failures occur. This should also ensure there are sufficient controls in place governing the use of override keys.

Picture archiving and communication systems (PACS)

Over the last year many trusts reached the end of contracts with their current PACS providers, which led to issues of data migration and the transition of legacy images to new PACS storage archives. We are aware of a number of incidents where PACS images have

been incorrectly profiled in patient folders and that audit trails of data migration and insufficient processes surrounding new image transfer have demonstrated weaknesses, which resulted in images being lost. This, combined with insufficient PACS and RIS housekeeping measures, has led to images being removed from local modality caches before the examination has been reported and error highlighted, resulting in repeat exposures.

Repeat exposures and checking examination history

Another trend is incorrect timing of follow-up imaging, usually for two reasons. Firstly, referrers may not be aware that they have to clearly identify the timing required for their patient's imaging, which leads to clerical staff making booking errors. Secondly, there may also be a lack of check back of previous imaging history and RIS reports at the point of justification/authorisation. We have received notifications where a patient attended hospital as an outpatient where a CT scan was requested, justified and appointed. Some days later the patient's condition deteriorated and they were admitted as an inpatient, where the same scan was requested, justified and carried out a short time later. However, the original (outpatient) scan request remained on the system, and the patient returned for this scan on the appointment date. Additional checks made on the day of the second scan may have alerted staff to this unnecessary repeat scan.

What CQC will do

We will collaborate with professions (Society and College of Radiographers, Public Health England and the British Institute of Radiology) to hold a workshop to raise awareness of a culture of radiation protection within radiology departments.

We will also work with healthcare professionals and partner regulators to raise awareness of the importance of ensuring that from referral through to x-ray and report, the intended patient receives the correct diagnostic radiology examination and outcome, including image archiving. We will meet with the Clinical Imaging Board to progress this strand of work. The Clinical Imaging Board comprises the three main professions involved in medical exposures (IPEM, SCoR, and RCR) and was formed following the disestablishment of the National Imaging Clinical Advisory Group.

What healthcare providers could do

We encourage providers to reflect on the information provided in this report, discuss relevant issues in local staff meetings and take account of any forthcoming guidance from professions in developing local IR(ME)R procedures.

Notifications in nuclear medicine

In 2013, there were 49 notifications involving nuclear medicine examinations. The table below shows the changes in rates of notifications since 2006-07.

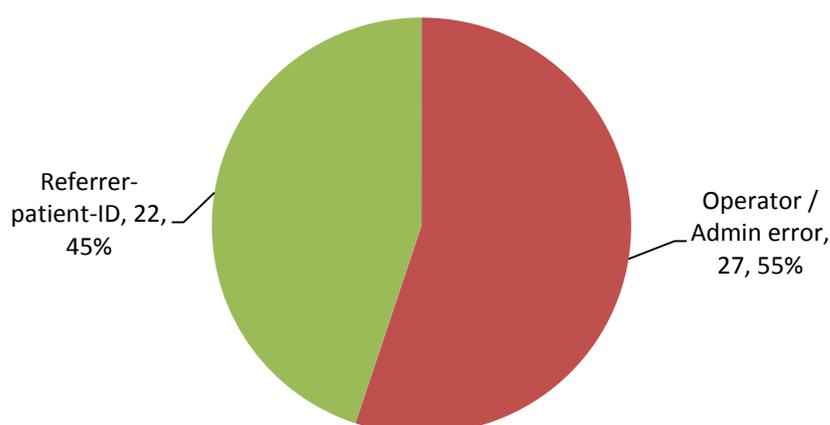
Nuclear medicine notifications:

2006-07	2008	2009	2010	2011	2012	2013
23	32	32	26	25	39	49

The data shows an increase in notification numbers in 2012 and 2013 from a mean value of around 27 in our first five years of enforcement.

As in previous years, the category of error in 2013 was broadly equally divided between referrer errors and those associated with operator errors, including incorrect administrations of radiopharmaceuticals. We are pleased to note that none of the notifications received in 2013 involved therapeutic exposures and we were not notified of any incidents involving foetal exposures or 'unknown pregnancy' at the time of administration.

Figure 6: Type of error (nuclear medicine 2013)



Referrer errors

Referrer errors were again a major source of notifications and included a variety of the types of incident seen in previous years. We have repeatedly drawn attention to concerns where patients who are meant to have a bone densitometry scan (for example, dual energy x-ray absorptiometry, or DXA scan) instead receive an injection of Technetium 99m radiopharmaceutical (for example, Tc99m MDP isotope bone scan) in error. Fortunately, in 2013 there were only two of these incidents. One of these was an electronic request where the two 'variations' of 'bone scan' were clearly identified but it was later reported that the junior doctor was not aware of the difference between them. It is important to draw attention to this potential confusion in hospital induction for junior doctors, and in IR(ME)R and electronic requesting training.

Similarly to diagnostic radiology, we also saw the usual category of notification involving referrers occasionally requesting nuclear medicine scans on the wrong patient – whether using electronic requesting or completing request forms. The learning already mentioned remains valuable. It is worth reminding IR(ME)R duty holders that at referral, authorisation and at the point of administration, they should always be alert to the risk of a patient identity error. Clinical detail and any available previous imaging should be checked in addition to patient demographics and the original request, rather than making checks against the list on the RIS.

Operator/administration errors

Notifications arising from operator errors and mistakes in administration followed a similar pattern to previous years. A significant number (approximately 15%) of all nuclear medicine notifications were as a result of the wrong radioactive medicinal product (RMP) being injected. Safe laboratory practice is the key to ensuring that the vial or syringe is correctly labelled, stored and available for administration, thereby minimising the risk of staff picking up the wrong injection.

The final patient identity check in nuclear medicine, as enshrined in the employer's procedures, must always be a 'three-way', patient identity v request v RMP about to be administered. In at least one notification, an operator misinterpreted the request and gave the patient a different anatomical scan and RMP from that intended. During 2013 there were no notifications arising from errors in the radio-pharmacy. These have the potential to carry increased risks and/or affect larger numbers of patients.

Cancelling requests made in error

Although it may not add up to a significant risk in view of the relatively small number of patients involved, we received five notifications in 2013 where referrers had realised that the request was at fault or the scan was no longer required and attempted to cancel the referral, only for the cancellation process itself to 'fail'. In one or two instances, communications were to blame and sometimes the 'timing' unfortunate. The cancellation process must be clear and will often include a direct phone call as soon as possible to the nuclear medicine department.

Isotope calibration error

In a few notifications, although the correct RMP was given to patients, it was the wrong level of activity as defined in guidance as 'MGTI'. These mostly resulted from human error and lapses in concentration or performance. In one instance five patients received relatively small overdoses when staff selected a wrong setting of the isotope calibrator. Elsewhere an operator read off a 'wrong' activity when looking at an activity chart.

Positron emission tomography (PET)/CT

Almost 20% of all nuclear medicine notifications arose from PET/CT, excluding those incidents that related specifically to the CT component. Some of the notifications had root causes as above, but a significant number compared to notifications associated with conventional gamma camera imaging, related to the operator equipment interface. These included errors in protocol, scan geometry, image registration or reconstruction, which could reflect the increased use and complexity in operation.

Despite the above commentary on the range and variety of notifications, and the recent increase in the number of notifications, one conclusion is that the number overall remains relatively small when compared with the number of tests undertaken using RMPs. Individually these errors are generally of low to medium risk, similar to those in diagnostic radiology.

What CQC will do

We will discuss our findings with healthcare professionals involved in providing nuclear medicine services, so that they understand the picture of notifications in this specialist area, and can help develop guidance where appropriate. We will meet with the Institute of Physics in Engineering and Medicine Special Interest Group for Nuclear Medicine. We intend to inspect nuclear medicine services and share our findings.

What healthcare providers could do

We encourage providers to reflect on the information provided in this report, discuss relevant issues in local staff meetings and take account of any forthcoming guidance from professions in developing local IR(ME)R procedures.

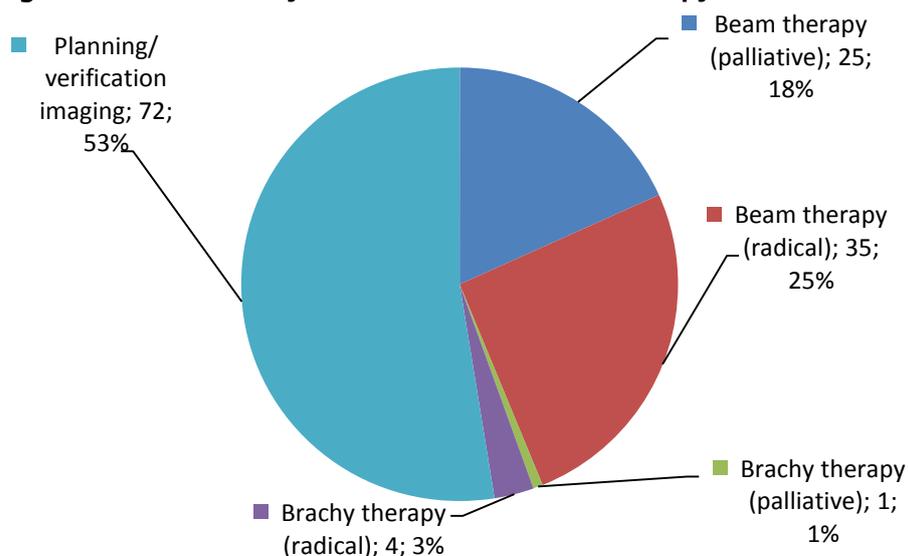
Notifications in radiotherapy

The revised guidance on the definition of MGTI for the ‘diagnostic’ higher dose category in September 2012 had an unexpected and significant impact on the number of notifications received from radiotherapy departments. These more than doubled in number, which was due entirely to receiving notifications involving treatment planning exposures and from ‘on-set’ verification imaging during treatment. As mentioned at the start of this report, in response to the above development and to effectively capture the data, we introduced a new radiotherapy sub-modality “planning/verification imaging” to the notification form, and which we describe as radiotherapy imaging (RTI) below.

Radiotherapy notifications 2006-07 to 2013:

2006-07	2008	2009	2010	2011	2012	2013 (RTI)
66	58	51	58	68	64	138 (72)

Figure 7: Sub-modality of notifications (radiotherapy 2013)



Though not shown separately in the above chart, of the 72 imaging notifications, 52 related to planning exposures, mostly repeat CT scans, and 20 to verification imaging where additional imaging was required due to problems with imaging or difficulties with the patient/treatment beam set up.

Planning exposures

The Department of Health's guidance on which repeat CT scans need to be notified excludes exposures that are "reasonable repeat exposures when any repeat is for technical/optimisation purposes rather than a procedural error". In radiotherapy planning, optimisation might be interpreted as improved planning performance in some way, but more importantly as facilitating improved targeting of the planned treatment volume and/or sparing of organs at risk. Looking at the 52 notifications that related to planning exposures, it is clear that they fell outside the 'exclusion' criteria in the Department of Health's guidance.

Service providers recognised that there had been a procedural failure of some kind, whether in CT protocol, scanning procedures, system, or operator performance, which should not have occurred. Most of the 'repeats' arose from mistakes by radiographers, for example, failing to follow protocol or read the request carefully, not covering the required scan volume or contrast medium delivery errors. Others arose from errors in referral where the clinical oncologist failed to adequately define the planning/treatment protocol or to accurately describe scan parameters or patient positioning. A small number of notifications related to 'unnecessary' planning scans, for example, resulting from 'timing' incidents where the planning CT had been authorised and duly performed, only for the planned treatment to be cancelled or where a prior cancellation decision had failed to reach the CT team.

Verification imaging exposures

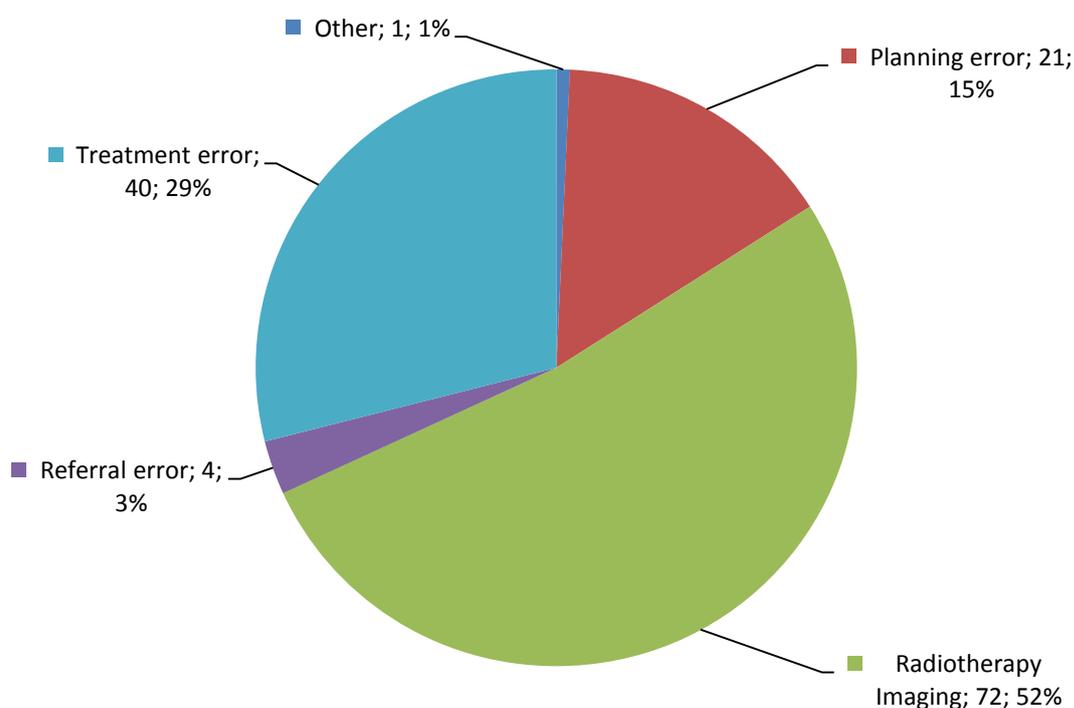
The situation regarding repeat MGTI verification images is perhaps more controversial. Over recent years 'on-set' imaging at the start of treatment, and periodically thereafter, has become commonplace, as the imaging protocol helps to verify patient/field positioning and prevents geographical miss and other treatment errors. In what is often referred to as

‘adaptive radiotherapy’ this is taken a step further; the on-set imaging becomes a tool for optimisation, with treatment staff determining what field or equipment ‘shift’ to make during the course of treatment. One notification described such a treatment where it was discovered towards the end of the course that 23 of the prescribed 33 fractions constituted a variety of geographical misses. Several shifts had been made through the course on the basis of the imaging, but when reviewed, all were found to have been inaccurate to various degrees. This would seem to be a valid case for notification and learning, as imaging is meant to facilitate improved beam targeting, but here had become a procedural failure and counterproductive with entirely the opposite effect on the geographic accuracy of the treatment delivery.

The verification image on day one of treatment is now routine and the majority of the 20 ‘verification’ notifications related to repeat exposures of that first image or where increased imaging outside of the protocol was necessary. A significant number of these notifications constitute an interesting category. Where the verification image prevents a ‘mismatch’ or an erroneous ‘shift’ going through to a geographical treatment miss, then clearly it is ‘doing its job’. There may have been a failure of some kind in set-up instructions, patient markings or matching of anatomy, but in this instance we have started to ask radiotherapy professionals whether the repeat image verifying the ‘correction’ should constitute an exposure MGTI, notifiable under Regulation 4(5).

We are initiating discussions on this to agree regulatory expectations and to inform any future MGTI guidance in this area that might emerge. This is likely to be part of a wider discussion between stakeholders. Having now received many notifications relating to planning and verification imaging over 18 months, it is apparent that there is a significant variation in practice across the radiotherapy community. Further clarity and agreement here would be worthwhile on both sides.

Figure 9a: Type of error (radiotherapy 2013)



Treatment exposures: referral/planning errors

Of the 66 notifications received over 2013 relating to incidents involving the treatment exposure, about a third arose from errors during planning and the remainder during treatment set-up or delivery. Only a few arose from errors or breakdown during referral or prescription. As mentioned in previous reports, although such incidents at the beginning of the patient pathway are relatively rare, they have the potential to remain undetected throughout the course of treatment and can constitute a significant risk. In one incident staff realised after two fractions of palliative treatment to the spine that cord compression had been diagnosed at different vertebrae to where treatment was prescribed.

Similar types of incident and outcome can also occur at the planning stage. For example, mistakes in outlining the CT planned target volume, or field placements with a simulator patient or errors in marking the fields on-set. These have the potential to translate to serious treatment incidents. In one notification, a patient was planned for palliative lung disease when treatment radiographers detected after two fractions that the wrong area was being treated. We have not observed any particular trend but, in this case, a locum clinical oncologist was involved and had marked up the upper lobe of the lung instead of the lower lobe despite the latter being clearly identified in all the referral and other documentation. In other clinical oncologist 'planning' incidents, the wrong side of the groin was treated for seven of 15 fractions and elsewhere a laterality error occurred when the right axilla was treated to 6.5Gy but the melanoma actually sited on the left side.

As in previous years, we have seen skin therapy incidents where identification of the site to be treated has proved ambiguous and mistakes made. It is a recurrent learning point that good liaison with dermatology colleagues is essential and that the clinical oncologist should always be provided with an accurate and unambiguous description of the lesion to be treated. In one such incident, control actions included the development and use of a dedicated referral form between the two departments.

The more common types of planning errors over 2013 that resulted in treatment delivery have been described in previous years' reports and include mistakes or breakdown in monitor unit calculation, lack of clarity and/or mistaken assumptions in treatment protocol, laterality mistakes, the wrong energy or fractionation and errors in data transfer and setup instructions. The use of 'DICOM' data transfer (Digital Imaging and Communications in Medicine) during system upgrades has again resulted in one or two notifications and it is clear that prior risk assessment and suitable training and preparation should be part of the planning.

Treatment exposure: set-up/beam delivery errors

As in previous years, the majority of treatment incidents over 2013 resulted from errors made when setting up the patient/field on the treatment machine – fortunately most comprising a 'single' fraction error often on the first day of treatment. These mostly resulted in geographical misses of varying degrees and often arise from an incorrect value or wrong direction shift, or for others, the wrong tattoo being mistakenly used as the reference point. The number of notifications in this latter category was similar to those notifications where the geographical miss originated from an anatomical mismatch from mostly online verification imaging against the digitally reconstructed radiograph by treatment staff. In several notifications remedial actions have included additional training and strengthening the competency framework. Elsewhere during 2013, a few notifications

and errors in treatment were caused by a failure of the patient identification procedure, resulting in one patient being treated with the plan of another. They usually arise from interruptions or amendment to the patient 'queue'. As mentioned in earlier years' reports, the final identity procedure in radiotherapy must always be against patient demographics, treatment sheet/plan and, importantly, the file selected on the patient management terminal.

Root causes in treatment incidents are often put down to 'human error', but the circumstances and contributory factors can vary a great deal. Involuntary automaticity¹, as described some years ago by Professors Brian Toft and Hugo Mascie-Taylor, continues to be mentioned in some notifications. It is also apparent that with the increased sophistication of set-up aids and verification systems, there is a danger that radiographer 'common sense' checks, for example checking the anatomy meant to be treated or viewing the applied field or light beam on the patient, can sometimes be forgotten. In one recent incident following a 'patient/plan identity' error, a patient requiring treatment to the brain was treated for part of one field from a prostate plan. A simple visual check would have shown the incorrect field placement. Fortunately in this case, the beam was soon terminated and there was little or no clinical impact from the irradiation. It seems clear that messages from the above paper and in other publications, such as 'Towards Safer Radiotherapy'², continue to have a part to play in how departments learn from errors.

Responsive inspections

As part of progressing radiotherapy notifications MGTI over 2013, we made visits to three NHS departments to investigate incidents in more detail than we could do by the usual email dialogue. One of these related to a serious incident where the prescription and planning in a treatment to the brain had failed to adequately spare the optic nerve. The discussions were a useful and necessary review of relevant treatment protocols to include organs at risk and their dose thresholds, and helped to improve understanding of IR(ME)R roles and responsibilities among clinical oncologists and other staff.

Another potentially serious incident concerned incorrect brachytherapy treatment of several patients, where some received a relatively small but notifiable overdose and others received marginally less radiation than prescribed. The difficulty arose when a new brachytherapy system was commissioned and introduced into service. Some time later, the new treatment delivery system and ovoids were found to be slightly different from those used previously and in the existing dose library. The brachytherapy service was subsequently suspended and the trust and individuals were open in their face-to-face discussions with us on how the error came about – a simple lack of 'visual' or 'sense' checks. There were contributory factors, and significant learning on several fronts including staffing, support, competency frameworks, strengthening the arrangements for commissioning of new equipment and how incidents were reported and escalated, including communication and structures into senior trust management.

¹ Brian Toft, Hugo Mascie-Taylor, Involuntary automaticity: a work-system induced risk to safe health care. *Health Services Management Research* 12/2005; 18(4):211-6

² The Royal College of Radiologists, Society and College of Radiographers, Institute of Physics and Engineering in Medicine, National Patient Safety Agency, British Institute of Radiology, *Towards Safer Radiotherapy*, London: The Royal College of Radiologists, 2008

We also visited a radiotherapy centre to progress a notification concerning treatment delivered to a patient, who was subsequently suspected not to have had cancer. The patient was treated with palliative radiotherapy to the brain over five fractions for an enhancing mass. The inspection gave us the opportunity to see images and treatment documentation, discuss the case directly with trust managers, clinical leads from diagnostic and treatment directorates across two trusts, and with those delivering care direct to patients.

What CQC will do

We will work with healthcare professionals at Public Health England, the Radiotherapy Board (itself formed from the disestablishment of the National Radiotherapy Implementation Group) and partner regulators to share our learning arising from notifications. We will inform professional opinion on our expectations and help initiate and develop guidance, in particular concerning notifications of relatively low risk planning and verification imaging, where there is a need for review and a more consistent performance across radiotherapy providers.

What healthcare providers could do

As above, we encourage providers to reflect on the information provided in this report, discuss relevant issues in local staff meetings and take account of any forthcoming guidance from professions in developing local IR(ME)R procedures.

3. Other activities

In this reporting year, our workload of investigating exposures ‘much greater than intended’ across all modalities increased significantly. At the same time, we underwent changes to our personnel. A new inspector joined us (replacing a colleague who had moved on), our business support was reviewed, analytical support was increased and legal support also underwent change. However, there was little or no increase in our capacity for our IR(ME)R work, or to provide support for colleagues with radiation protection concerns arising from registration or compliance work from the Health and Social Care Act. Although this compromised our capacity to give proactive compliance support, it allowed us to focus on ensuring, as best we could, that we investigated each notification to a conclusion in as timely a way as possible.

In 2013 we supported a scientific programme developed by the UK Radiology Conference in Liverpool. We participated in a separate event organised by the British Institute of Radiology in its ‘IR(ME)R Update’ in Birmingham in June. We were also invited to support a regional radiation protection training event in the south east of England attended mainly by radiographers intending to become departmental Radiation Protection Supervisors.

4. Work in 2014 and beyond

Our plans for 2014

1. We look forward to discussing our work with partner IR(ME)R enforcement authorities, regulators and their advisers and healthcare professions. This work could possibly influence and inform decisions concerning the framework for enforcing patient protection regulations and the notifications guidance in the longer term, ‘pan-European’ regulatory structures from 2018 onwards.
2. Our priority for 2014 is to re-establish a core team for our planned inspection programme in radiology, to support the increasing number of notifications of exposures MGTI and to provide specialist support for CQC colleagues under the Health and Social Care Act when working in radiology, radiotherapy and nuclear medicine departments. We will assess how our work can inform colleagues with wider enforcement powers across the acute and primary care sectors as part of their inspection programmes.
3. We will work closely with colleagues to ensure that our IR(ME)R enforcement work, in particular inspection, is aligned with the new inspection methodology being adopted and developed within CQC across acute and primary care sectors.

4. We will work with colleagues with wider enforcement powers in relation to providers of CT scans of the 'worried well'.
5. We will continue to share our findings and wider learning from notifications and lessons learned from errors with professions. We see this as a potential opportunity for organisations to improve how they deliver care to patients. The work with the Radiotherapy Board and the Clinical Imaging Board may also lead to guidance from the profession to members to mitigate risks arising from medical exposures, and may make proposals for revised guidance on notifications.

5. Conclusion

Notification of exposures ‘much greater than intended’ and our investigation of each individual case provided a major challenge during the year. In 2013, we received almost 1,000 notifications, an increase of nearly 50% since the previous year and a three-fold increase on the totals in our first 14 months in 2006-7. The number of notifications has continued to rise across all modalities. We are not aware of any evidence which suggests that medical exposure is subject to increased rates of error per patient episode. Rather, we believe that the increased reporting is a positive impact on safeguarding patients undergoing x-ray procedures, radiotherapy treatment and nuclear medicine examinations. We believe the increase arises because of:

- a. The change in guidance published by the Department of Health and a reduction in the threshold for some exposures, principally computed tomography.
- b. The confidence of healthcare organisations in our approach.
- c. An understanding that notifying the enforcement authority will, in itself, demonstrate transparency and facilitate improved learning both locally and across the community. It is worth reiterating that the findings here represent an excellent illustration of how transparent reporting can lead to learning and improvement through regulation.

In this report we discussed the impact of the error on patients. This may be based on established dose/risk estimates, and more subjective issues that arise when a patient is told about an error that involves them. We believe this approach is more in line with CQC’s wider methodology. More views are likely to be forthcoming from radiation healthcare professionals on duty of candour relating to medical exposures, taking account of the circumstances of the individual patient, exposure, intent and modality, set against the magnitude of the radiation risk and the potential detriment in causing undue anxiety, especially where the difference between the two may be disproportionately large. The support offered to patients in those cases where the patient is informed is clearly important, as is how and when such patients (or their relatives) are informed.

Clearly, the potential hazards arising from errors in treatment delivery exposures could be significant. Many radiotherapy ‘treatment errors’ notified to us are correctable in subsequent patient attendances, but some will limit the success of the intended treatment. Nuclear medicine treatments are ‘single fraction’ by their nature, and errors usually not correctable in any way. Errors in diagnostic radiology or nuclear medicine may result in small increases in dose and risk in comparison with the overall probabilities that we may develop and/or die from cancer. Additional risks include those arising from misdiagnosis and misfiling of images into the folders of other patients, along with risks arising from any subsequent tests and/or interventions.

Overall, 2013 was a challenging year for the IR(ME)R team with a vastly increased workload set alongside wider changes in CQC. By necessity our activities were focused on investigating notifications made to us of exposures ‘much greater than intended’ and supporting CQC inspectors and registration colleagues when they came up against concerns in the specialised field of radiation protection, whether in hospital x-ray, radiotherapy or nuclear medicine, or more commonly, in the field of primary care dentistry.

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