Ionising Radiation (Medical Exposure) Regulations 2000

A report on regulatory activity in 2010

April 2011
About the Care Quality Commission

The Care Quality Commission is the independent regulator of health care and adult social care services in England. We also protect the interests of people whose rights are restricted under the Mental Health Act.

Whether services are provided by the NHS, local authorities, or by private or voluntary organisations, we focus on:

- Identifying risks to the quality and safety of people’s care.
- Acting swiftly to help eliminate poor-quality care.
- Making sure care is centred on people’s needs and protects their rights.
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Summary

This is the fourth annual report on regulatory activities in enforcing the Ionising Radiation (Medical Exposure) Regulations 2000 (IR(ME)R).

The regulations were established to ensure that all medical exposures in diagnosis, treatment, research and screening are individually justified and optimised.

Inspection activities

In 2010, we conducted four inspections of cardiology departments and two inspections of radiotherapy departments. We continued our pilot inspection programme in chiropractic and dental, having inspected eight clinics to date, and we plan to summarise these findings in a separate report in due course.

We have also visited hospitals to gather information in response to notifications and in response to information provided to us by whistleblowers.

We published a report summarising the findings from our first 31 proactive inspections of radiotherapy departments in England carried out during 2007 to 2009, which is available at: www.cqc.org.uk/publications.cfm?fde_id=17183.

Exposures 'much greater than intended'

Under regulation 4(5), healthcare organisations are required to notify us of exposures to patients that are 'much greater than intended'.

In 2010, we received a total of 494 notifications, reflecting a continuing upward trend in terms of the number of monthly notifications.

The variation of notifications made by geographical region in 2010 is more pronounced than ever, with the rate of notifications in the East Midlands more than twice the mean from England as a whole.

To help get an overall picture of activity, we compared the rate of notification to us in England with the total number of medical radiation examinations conducted. We estimate that we were notified of one error in over 81,000 examinations.

We received 410 notifications from diagnostic radiology. Approximately half of these involved patient identification errors, either because the wrong patient was referred for X-ray examination, or because operators failed to follow the patient identification procedure and X-rayed the wrong patient. An increasing proportion of notifications is arising from errors made in computed tomography (CT) scanning. However, most notifications from radiology departments in 2010 were assessed to be 'low-dose', i.e. less than 1mSv, and therefore present very little additional risk to patients involved.
There were 26 notifications involving nuclear medicine examinations, which is similar to previous years.

Notifications from radiotherapy departments have remained steady over the previous three years; there were 58 notifications in 2010, compared with 51 in 2009. Overall, the notification rate remains at approximately one a week.

We have provided examples in Appendix B of notifications received in 2010, and examples of errors and local solutions that organisations put in place to prevent a repeat error. We hope these continue to be helpful to departmental managers when reviewing their own local strategies and procedures as required by the regulations.

**Supporting the new system of registration**

During the year, members of the IR(ME)R team contributed to CQC’s registration activities, drafting guidance documents for colleagues, conducting joint registration compliance assessments where the provider carried out radiology activities, and contributing to policy development.
Our Work in 2010

Proactive inspections

In 2010, we carried out four compliance inspections of cardiology departments, completing our planned inspection programme in that area. The first five cardiology inspection reports were published on our website in 2009 and the final four inspections will be published later in 2011.

We intend to publish a separate summary of the findings for these inspections in the same way as we did following our earlier inspections of radiotherapy departments. The overall findings of our inspections in cardiology were:

- Inadequate operator or practitioner training of cardiologists and record keeping, including shortcomings in evidence of training related to the adoption of new clinical techniques.
- Inadequate understanding of patient doses by cardiologists.
- Inadequate sign-off or approval of employer’s procedures in cardiology.
- Inappropriate use of radiology procedures within the cardiology department.
- Poor understanding of how exposures had been authorised.

We also conducted two proactive compliance inspections of radiotherapy departments. One of these inspections was as a result of a notification received where the timing of radiotherapy treatment was not as intended, and the other because of the lack of any notifications made since CQC had assumed enforcement responsibilities for IR(ME)R in November 2006. In this case, we looked for assurance on the identification, review, escalation and management of near-misses, non-conformances to the quality management systems, and other errors that might have been notified by other clinical departments.

The remaining inspections in 2010 were conducted in dental and chiropractic. After completing a small number of inspections of dental practices during early 2010, this inspection programme was temporarily postponed until the conclusion of the Health and Social Care Act 2008 registration process, under which all dentists were required to apply for registration by 1 December 2010 and must be registered by 1 April 2011.

Our programme of inspections in chiropractic continued during 2010 and although the total of eight inspections is a small sample, we believe it is representative of the picture in England. We have met with stakeholder organisations and given verbal feedback on our findings, and intend to publish these in a thematic report on IR(ME)R compliance in chiropractic. Our policy in 2010 was to write to individual chiropractors in the form of an ‘exception’ report, describing both areas of non-compliance and also where compliance could be improved. In line with our standards elsewhere, we require chiropractors to confirm, within three months, their actions in response to our recommendations.
Our summary report in chiropractic X-ray will show that, 10 years after IR(ME)R was introduced, compliance across the chiropractors visited was generally poor, especially when compared with our assessment of IR(ME)R compliance in general radiology and elsewhere. We recognise that chiropractic X-ray is clinic-based and comparable to the use of X-ray in dental surgeries, though we acknowledge the patient doses, and therefore risks, are somewhat greater. It is clear that the service and support provided to the chiropractor by the medical physics expert required under IR(ME)R is key to the process, particularly in drafting or providing help with producing the employer’s written procedures. We have therefore met with representatives of organisations providing such services and given informal feedback on our findings.

All our inspections were ‘announced’, in that we gave notice to the organisation’s chief executive of the date, agenda and expectations of the inspection, including who we required to participate in the inspection, details of documentation required in advance, what clinical areas we wanted to visit and an outline timetable.

Nevertheless, we view unannounced and short-timescale inspections (such as a phone call from us explaining “there will be three of us coming to inspect tomorrow morning at 9.30”) as a valuable way of assessing the compliance of radiology departments, and we will use this format where appropriate.

Reactive inspections

When we receive specific concerns from whistleblowers or members of the public, or when we receive a notification of an exposure much greater than intended that stands out from others, we have the authority to gather evidence directly by visiting the hospital or to conduct a reactive inspection. This includes the authority to take witness statements and to conduct our own recorded interviews of witnesses and suspects.

In 2010, in response to notifications made by radiology and radiotherapy departments in England, we decided that in two instances it was appropriate to investigate further by visiting the organisation and discussing the factors leading to the error directly. The first was the error in timing of radiotherapy treatment delivery, mentioned above. The second visit was in response to a notification from a radiology department where adult radiographic factors had been set for a CT scan of a young child.
Notifications of exposures 'much greater than intended', regulation 4(5)

Guidance on making notifications

In 2010, we updated the information on our website relating to notifications. The guidance for reporting such exposures is published by the Department of Health, and is available online at: www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4007957.

The Department of Health initiated a review of notification trigger levels in 2008, and asked for contributions from enforcement authorities and specialist advisers in the Health Protection Agency. At the time of publishing this report, the department is preparing for a consultation with healthcare professionals across all clinical disciplines about their interpretation of ‘much greater than intended’. CQC made a significant contribution to these discussion documents to help determine strategies for the consultation and we will continue to provide support through to the introduction of new guidance.

Part of this dialogue included providing an analysis of doses received by patients who had received a diagnostic radiology examination in error, leading to an exposure much greater than intended. More information on this is provided in the diagnostic radiology section on page 10.

Notifications in 2010

In 2010, we received 494 notifications, reflecting a continuing increase in the rate of notifications received since November 2006 (we received 482 in 2009, 403 in 2008 and 329 in the first 14 months of enforcement, November 2006 to January 2007). Although there is an upward trend in terms of the number of monthly notifications received, there was some evidence of a plateau since last year (Figure 1).

We believe that a large percentage of notifications are the result of good governance practice. These include the voluntary notification of errors that were not ‘strictly’ much greater than intended, but were shared to promote a wider understanding of errors and solutions for the wider benefit of colleagues working in the same discipline.
Our annual analysis of the variation in rates of reporting across England now shows a marked variation across strategic health authority (SHA) boundaries. We looked at the number of notifications of exposures that were much greater than intended, including those that were ‘volunteered’ to us, and have taken account of the relative populations within each SHA. Again, we have assumed that the number of radiology examinations is consistent across the country.

The variation in 2010 is more pronounced than ever, with the rate of notifications in the East Midlands more than twice the mean from England as a whole. This variation may be a result of those organisations adopting policies of notification to external authorities that are different to the others, perhaps supported by their colleagues in clinical governance and specialist expert medical physics staff.
Figure 2: Percentage of notifications made by SHA regions in 2010
Notifications in diagnostic radiology

In 2010, we received 410 notifications from diagnostic radiology. Analysis of the same datasets from previous years has shown no fundamental differences (see Appendix A). We estimate that around half of notifications from diagnostic radiology involve the ‘wrong patient’ – whether they were referred incorrectly or whether operators failed to follow the established patient identification procedure and X-rayed the incorrect patient.

We have noticed an increasing proportion of notifications arising from errors made in computed tomography (CT) scanning since 2008.

Percentage of diagnostic radiology notifications from CT scanning

<table>
<thead>
<tr>
<th>CT notifications</th>
<th>2010</th>
<th>2009</th>
<th>2008</th>
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</thead>
<tbody>
<tr>
<td>% of total</td>
<td>43%</td>
<td>43%</td>
<td>33%</td>
</tr>
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</table>

This is a cause for concern when viewed alongside the outcome from the Health Protection Agency’s frequency and dose survey report: www.hpa.org.uk/Publications/Radiation/CRCEScientificAndTechnicalReportSeries/HPA CRCE012/.

This shows that over two-thirds of all the dose delivered by radiology departments is attributable to CT scans. In 2010, 204 (50%) of the notifications arose from examinations involving 2D projection radiography, followed by a smaller proportion (177 notifications, 43%) of notifications involving CT scanners.

Figure 3: Type of error (diagnostic radiology 2010)
**Figure 4: Submodality of notifications (diagnostic radiology 2010)**

- 204 Notifications (49.8%)
- 177 Notifications (43.2%)
- 6 Notifications (1.5%)
- 4 Notifications (1.0%)
- 2 Notifications (0.5%)
- 1 Notification (0.2%)

**Figure 5: Distribution of patient doses in notifications from diagnostic radiology in 2010**

Dose level of diagnostic incidents under IR(ME)R regulation 4(5) - exposures "much greater than intended" - 2010

- CT
- DEXA
- Fluoroscopy
- Rad CR DR
- Interventional
- Cardiac
- Mammography
- Dental

<table>
<thead>
<tr>
<th>Dose Level mSv</th>
<th>Frequency</th>
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<tbody>
<tr>
<td>0-1</td>
<td>177</td>
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<tr>
<td>1-2</td>
<td>43.2%</td>
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<tr>
<td>2-3</td>
<td>4</td>
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<tr>
<td>3-4</td>
<td>1.5%</td>
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<tr>
<td>4-5</td>
<td>6</td>
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<tr>
<td>5-6</td>
<td>1.5%</td>
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<tr>
<td>6-7</td>
<td>2</td>
</tr>
<tr>
<td>7-8</td>
<td>0.5%</td>
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<tr>
<td>8-9</td>
<td>1</td>
</tr>
<tr>
<td>9-10</td>
<td>2</td>
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<tr>
<td>10-11</td>
<td>0.5%</td>
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<td>11-12</td>
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Figure 5 shows estimates of the doses given to patients in 404 of the 410 notifications received arising from errors in diagnostic radiology exposures in 2010. The majority of doses received by patients involved in such errors are clearly at the lower dose levels. In fact, the majority of errors arise from 2D projection radiography (called Rad CR DR in Figure 4), with most of these involving the wrong patient undergoing an X-ray.

Just fewer than half the notifications we receive in diagnostic radiology involve the patient receiving an effective dose of less than 1mSv, and therefore, in general, patients are not put at significant risk from the dose arising from the exposure made in error (using risk factors of 5%/Sv, in accordance with International Commission on Radiological Protection (ICRP) methodology). We shared this data with enforcement colleagues and policy makers as part of our contribution to the revision of guidance about what constitutes ‘much greater than intended’. We have not produced equivalent data in nuclear medicine or radiotherapy.

Although the dose and risk to individual patients is, in most cases small, the fact that an error has occurred, and that procedures designed to detect errors have failed, is important to responsible healthcare organisations, which then go on to notify CQC. One such organisation included a comment that in making notifications to us “transparency is a key driver in transformational change”.

We provide some examples of notifications from 2010 in Appendix B.

**Notifications in nuclear medicine**

In 2010, there were 26 notifications involving nuclear medicine examinations, which is similar to previous years (32 in 2009, 32 in 2008 and 23 in the 14 months to the end of 2007). The number of notifications is relatively small compared to those in diagnostic radiology. We believe this result corresponds to a reduced frequency of medical exposures in nuclear medicine, together with additional regulations and the many safeguards in place concerning the manufacture, transport, storage, administration, scanning, record-keeping and disposal of radioactive material.

Just one notification related to a therapy administration of a radiopharmaceutical, a thyroid ablation treatment using iodine-131. Although there had been no breakdown of practice in IR(ME)R regarding the procedure on asking about pregnancy, it transpired that the patient unknowingly was in the early stages pregnancy at the time of treatment. In such cases, we receive the necessary assurances that risks were assessed and the patient advised accordingly. Providers appear to report such incidents to us because the foetal dose is much greater than intended and the risks will be significant, at least in therapy. Over recent years we have received several similar notifications relating to irradiation in pregnancy from nuclear medicine examination or treatment. There is a variety of practice relating to how healthcare staff conduct the ‘pregnancy question’ and we hope to ask the professions whether they are able to create guidance on best practice in this area for the benefit of both staff and patients.
Of the 25 notifications involving errors in diagnostic nuclear medicine administrations, as elsewhere, the most common cause was again referrer error resulting in the wrong patient being administered with radioactive material, sometimes on the ward. There have also been several examples where the error was recognised by the referring department and the examination cancelled, but the arrangements were unclear and they did not stop the administration in time.

**Figure 6: Type of error (nuclear medicine 2010)**

In 2010, arrangements for outsourcing examinations involving nuclear medicine have featured in notifications. Whether provided by a specialist NHS unit or by a provider from the independent sector, it is apparent that the arrangements and procedures to refer the correct patient or to cancel booked scans to prevent inadvertent or unnecessary exposures are not always clear.

We note that another common cause of unintended nuclear medicine administrations arose from X-ray and MRI requests being mistakenly routed or booked for nuclear medicine examination. Often administrative and clerical staff in the imaging department were involved or responsible. We note that these staff are rarely entitled as IR(ME)R operators, and the remedial action taken addresses a ‘system’ error. However, it is perhaps surprising that if such an error results in an unintended exposure, then it must have been duly authorised and performed by their IR(ME)R practitioner and operator. It does reinforce the need for care and scrutiny at all stages in the referral, authorisation and optimisation process by all concerned.

A root cause or contributory factor here is also often the actual request and we recognise that referrers are reminded by their organisation to be accurate and explicit about the nature of the requested examination and modality, in addition to ensuring they have referred the correct patient. In Appendix B, we describe how referrers should avoid non-specifics such as “bone scan” and abbreviations that may be easily misinterpreted.
Notifications in radiotherapy

We note that the numbers of notifications from radiotherapy departments have remained steady over the previous three years. There were 58 notifications from radiotherapy departments in 2010, compared with 51 in 2009, 58 in 2008 and 66 in the 14 months to the end of 2007. Overall, the notification rate remains at approximately one a week. A tiny proportion of errors arise from the use of brachytherapy devices.

At the end of 2010, there remained two radiotherapy departments of the 50 in the NHS in England that had still not notified us of a single error leading to an exposure much greater than intended since November 2006. In 2010, we received our first notification from one of the eight radiotherapy providers in the independent sector in England. The lack of notifications alone was itself sufficient to prompt us to carry out a proactive inspection late in 2010 at a major NHS provider of radiotherapy services. We summarise some of the main findings from our investigations of errors in radiotherapy departments in Appendix B.

Overall, it is reassuring to note that with the increasing use of ‘in-beam’ verification imaging before and during treatment, many errors occur for one fraction only before being discovered. However, imaging is not always fail-safe and we have noted several instances where the check has failed, perhaps as a result of poor performance by staff or inadequate image quality. The extension of ‘day zero’ checks before starting the treatment is also an increasingly common strategy taken by departments in to reduce errors during the initial treatment set-up.

Geographical misses in treatment constitute the most common type of notification in radiotherapy and we note that many departments appear to report these to us as exposures much greater than intended when the degree of miss exceeds the normal gross tolerance for a particular treatment, or when the intended dose to an organ at risk is exceeded by the usual multiple. We hope that those in the professions will be able to contribute to this topic in the Department of Health’s consultation on its guidance on what constitutes ‘much greater than intended’ in the future.

Figure 7: Type of error (radiotherapy 2010)

- 18 Notifications (31%) - Planning error
- 4 Notifications (7%) - Referral error
- 36 Notifications (62%) - Treatment error

Care Quality Commission  IR(ME)R: A report on regulatory activity in 2010
Notifications from individual organisations

At the end of 2010, 17 NHS acute trusts had not made one notification to CQC from any modality or clinical department using radiation about an exposure much greater than intended. It is open to interpretation whether this reflects positively on the organisation, arising from good practice, governance, staff training and attention to detail, or whether the departments simply have no idea what constitutes an error much greater than intended or they are unwilling to disclose information. As far as we are aware, none of the 17 trusts have employed their own medical physics expert, but instead contract services out to nearby or regional service providers.
Other activities in 2010

Rates of notification to CQC as a proportion of activity in England

To help get an overall picture of activity, we have estimated the error rate of medical exposures in England. We compared the notifications received in 2010 with data for 2008 in a report from the Health Protection Agency, published in the first few days of 2011 *Frequency and Collective Dose for Medical and Dental X-ray Examinations in the UK, 2008.*

NHS organisations are required to submit returns to the Department of Health about the number of imaging and radio-diagnostic examinations (known as KH12) each year. The data for 2009/10 showed that the NHS in England has increased activity by over 3% since the previous year 2008/09.

The HPA report was a helpful source of information and analysis relating to the number of examinations (rather than number of individual exposures), particularly with estimates for the independent sector. It stated that there were 46.1 million radiology examinations in the UK in 2008; from this we estimate that there were 38.7 million carried out in England. We also included data from the National Cancer Services Analysis Team, which showed that 1.6 million radiotherapy treatment exposures were carried out in England (data excludes planning exposures, orthovoltage and brachytherapy exposures, all radiotherapy and nuclear medicine exposures from the independent sector). From this, we estimate that we were notified of one error in over 81,000 examinations.

This figure is likely to over-estimate the error rate as it does not include all exposures and a significant proportion do not meet the notification criteria, but have been reported to us in any case. In addition it is worth noting that the vast majority of these errors occur in diagnostic radiology and the dose or risk to the individual patients affected is very small.

We believe this is a low rate, which is due to a number of factors including: good training for clinical staff; an awareness of the importance of quality assuring practice and procedures; assessing the competence of staff and involving specialist physics experts, as well as good organisational governance and a degree of openness with the regulator. We acknowledge that there may be under-reporting of notifications from some organisations.


Registration and IR(ME)R

We have actively participated in CQC’s efforts to develop and integrate IR(ME)R inspection and enforcement activities alongside the registration of health care organisations in England by providing specialist support and advice to colleagues assessing applications.

We developed and piloted a template of Q&As for assessors and inspectors to use during registration visits, and have also provided specialist advice both on and off site during visits to providers.

Informing a bigger picture of errors in radiotherapy

We have now published our retrospective summary of findings from our first 31 compliance inspections of radiotherapy departments, which we hope will help those departments reviewing their own policies and procedures. We also gave the Health Protection Agency access to our database of closed, anonymised radiotherapy notification/investigation files to enable them to code the errors according to those described in Towards Safer Radiotherapy: www.nrls.npsa.nhs.uk/resources/?EntryId45=61646

This allows them to build in the ‘mandatory’ notifications and analyse them alongside non-mandatory errors and near-misses reported to the National Patient Safety Agency. HPA provides an overview of its analysis of radiotherapy errors in its quarterly bulletin: Safer Radiotherapy, available at: www.hpa.org.uk/ProductsServices/Radiation/Radiotherapy/RadiotherapyNewsletters/

Joint meeting of all IR(ME)R enforcement authorities and other national stakeholders

In the summer of 2010, we took part in a meeting of all IR(ME)R enforcement authorities, the HPA, colleagues from the Republic of Ireland and the Department of Health. The meeting was hosted in Dublin by the Health Services Executive, the enforcement authority for SI 478/SI 303 in the Republic of Ireland, the broad equivalent of IR(ME)R. It was the second such summit. It allowed us to share experiences and approaches to inspection and to be updated on likely changes in regulatory structures at a European level.

Presentations of our activities

We presented IR(ME)R enforcement activities at only one scientific meeting in 2010, at a national conference for radiation protection supervisors in the south east of England. We also presented a talk at a scientific meeting on paediatric radiology organised by the British Institute of Radiology called ‘IR(ME)R 2000 – notifications involving children in England’.
Interest from the media

In May 2010, shortly after we published our 2009 report, we responded to an enquiry made under the Freedom of Information Act asking for information relating to the numbers of notifications made to us, the dose multiplier value and the number of notifications from each provider in 2009. However, it was not until January 2011, as we were compiling the data for this report, that we learned how this information was to be used in an article in a national Sunday newspaper entitled "Hundreds a year hit by X-ray overdoses". The article included the identity of three NHS trusts that had made notifications to us but without any scientific analysis and ignoring the contextual information that we provided. It also included references to incidents reported to the Health and Safety Executive of over-exposures under the Ionising Radiations Regulations 1999.

Late in 2010, we became aware of an article published in the Clinical Radiology journal 65 (2010) 984-988 about a radiology department. Its authors had conducted a clinical audit looking into the rates of written clinical evaluation of the outcomes of medical exposures where there was an established agreement that such a 'report' would be provided by the referring clinician from chest, maxillo-facial, rheumatology, orthopaedics and inpatients. The article identified that referring clinicians had not recorded a written clinical evaluation report in patients' notes for approximately 50% of exposures. In response, our letter to the editor points out that the department in question is taking steps to improve compliance with regulation 7(8). Our letter has been accepted for publication sometime in 2011.

IR(ME)R definition of the employer

We have frequently been asked about the definition of 'the employer' in circumstances when two providers collaborate to provide a clinical service, such as when an NHS trust contracts with a provider from the independent sector to provide a CT, PET-CT or cardiology service for the trust's patients. The definition of 'employer' can be found in Regulation 2. Our legal advisers have interpreted the employer to be 'the organisation on whose behalf the medical exposure is carried out', that is, the organisation that has the contract with the patient, or the company/body requesting the exposure, or who has responsibility for providing the medical exposure. Where a trust has a service level agreement with an independent provider to undertake any ionising radiation work, the trust would be the 'employer' as this would fall within 'engages others to carry out'.

Communication with other stakeholders and professional bodies

We always make a point of meeting with the healthcare professions and fellow enforcement authorities to share our inspection findings as well as the findings of investigations of exposures much greater than intended. We also discuss issues of policy as they relate to the wider enforcement of medical exposures.
In 2010, these bodies included the Department of Health, the Health Protection Agency, IR(ME)R enforcement authorities from, Scotland, Northern Ireland and Wales, and professional organisations such as the Royal College of Radiologists, the Society and College of Radiographers, the Institute of Physics and Engineering in Medicine, the British Institute of Radiology and with other enforcement authorities, such as the Health and Safety Executive and the Medicines and Healthcare products Regulatory Agency. We have actively supported committees of the Institute of Physics and Engineering in Medicine and the British Institute of Radiology that are active in medical radiation protection.

We also engaged with overseas organisations with similar responsibilities including the Health Services Executive in the Republic of Ireland, and we hosted a short meeting with a consultant working on behalf of the Israeli Ministry of Health.
Next steps

We intend to develop our inspection programme for 2011/12 in core radiology activities, and hope to make specific enquiries about CT scanning services. The report from the Health Protection Agency, cited earlier, noted that diagnostic CT scanning accounts for 68% of the collective dose from all medical and dental X-ray examinations, despite comprising only 11% of the total number of examinations.

In last year’s report, we indicated that we would start to inspect organisations that provide CT scanning services to people who have no symptoms. Although we have not yet begun this, we have met with one such provider, and worked with colleagues to develop arrangements to register these organisations under the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 and the Care Quality Commission (Registration) Regulations 2009. The organisations were subject to registration from October 2010. These services continue to be the subject of some concern among healthcare professionals. It should be noted that registration of healthcare providers is a process in addition to IR(ME)R inspections, not a replacement for it, and we will ensure that inspecting these organisations is a priority for 2011/12.

We continue to monitor developments in the USA concerning the use of CT scanning to assess patients suspected of having a stroke. The Food and Drug Administration in the USA has recently requested the dose display requirements of CT scanners to be amended. In addition, we are aware of articles appearing in US newspapers drawing attention to patients who have suffered adverse effects following radiotherapy treatment. The circumstances of these errors, and why patients have been affected, are not yet clear and may never be so.

The difference in regulatory frameworks in Europe and the USA has long been recognised. In Europe, we have implemented national legislation such as IR(ME)R following recommendations made by the International Commission on Radiological Protection, (ICRP 60 and ICRP 103) and the formulation of Euratom Directives. We welcome the renewed awareness in the USA and acknowledge that we too can learn from initiatives in the USA to restrict doses, for example in children, as part of the Image Gently campaign. The Department of Health called a cross-agency meeting to determine whether a UK response was required to the events in the USA.

How we will manage notifications

In our annual report of IR(ME)R activities for 2009, we explained how we manage notifications of exposures made in error. We have used a commercially available webform notifications system since 2008, which we will continue to use until later on in 2011, when we will adopt a new system to be used across CQC. This is designed to manage a range of communications from providers, including the submission of IR(ME)R notifications. We will tell healthcare professionals about any changes to the arrangements for making IR(ME)R notifications, and about any changes to the Department of Health’s guidance on notifications after the consultation exercise.
We are considering alternative arrangements for communicating with organisations as we investigate notifications reported to us. This may include a brief telephone exchange to clarify circumstances and a simple email to the ‘notifier’ and the organisation’s chief executive, rather than a conventional hand-signed, posted letter.
Appendix A: Notifications of exposures much greater than intended

Numbers of notifications

Diagnostic radiology

Figure 9: Submodality since July 2007 (diagnostic radiology)

Figure 10: Type of error since November 2006 (diagnostic radiology)
Additional analysis of notifications in diagnostic radiology over our first four years of enforcement

Figure 11:

Type of Error: Diagnostic - Nov 2006 - Dec 2007

Notifications = 240

- Operator error: 84 notifications (35%)
- Referrer - patient ID: 25 notifications (10%)
- Repeat X-ray: 24 notifications (10%)
- Wrong anatomy: 2 notifications (1%)
- Other: 105 notifications (44%)

Figure 12:

Type of Error: Diagnostic - 2008

Notifications = 312

- Operator error: 156 notifications (50%)
- Referrer - patient ID: 77 notifications (25%)
- Repeat X-ray: 38 notifications (12%)
- Wrong anatomy: 38 notifications (12%)
- Other: 3 notifications (1%)
Figure 13:

Type of Error: Diagnostic - 2009

Notifications = 399

- Operator error: 197 notifications (49%)
- Referrer - patient ID: 66 notifications (17%)
- Repeat X-ray: 45 notifications (11%)
- Wrong anatomy: 119 notifications (30%)
- Other: 1 notification (0%)

Figure 14:

Type of Error: Diagnostic - 2010

Notifications = 410

- Operator error: 179 notifications (44%)
- Referrer - patient ID: 66 notifications (16%)
- Repeat X-ray: 45 notifications (11%)
- Wrong anatomy: 119 notifications (29%)
- Other: 1 notification (0%)
Nuclear medicine

Figure 15: Sub modality since July 2007 (nuclear medicine)

11 Notifications
11%

86 Notifications
89%

Diagnostic
Therapeutic

Figure 16: Type of error since November 2006 (nuclear medicine)

12 Notifications
11%

55 Notifications
48%

46 Notifications
41%

Foetal exposure
Referrer - patient ID
Operator/admin error
Radiotherapy

Figure 17: Submodality since July 2007 (radiotherapy)

Figure 18: Type of error since November 2006 (radiotherapy)
Appendix B: Issues arising from investigating notifications

Diagnostic radiology

Electronic requesting systems
In 2010, errors made by referrers using electronic requesting systems relate to specific issues including:

- Referrer not logging on or logging off properly.
- Referrer’s lack of awareness of the identity of the correct patient, and of ‘screens behind screens’.
- Lack of specificity in relation to who has been entitled to request the system, providing only an ‘all-or-nothing’ approach – particularly in relation to non-medical referrers.
- Lack of access to nationally-procured systems to re-design local solutions.
- Referrers ignoring pop-up dialogue boxes warning ‘are you sure you have the right patient/exam’?

Guarding against repeat examinations
Organisations have developed local arrangements to enquire whether patients have recently undergone similar or identical examinations, as a guard against an unnecessary repeat exposure. We have noted that a number of different workers and operators under IR(ME)R have been designated this authority, including administrative and clerical staff, radiographers, and radiologists.

Non-medical referrers for CT scans
We have received several enquiries concerning non-medical referrers (mainly specialist nurses) who have often only completed a brief awareness training of the legal context for referrals, and are beginning to be entitled to refer not only for conventional 2D radiographs but for CT scans, where such requests are part of an established care pathway. Although we do not record them separately, we are aware that there have been only a few referral errors from non-medical referrers. This gives us reassurance that arrangements to train, assess, and entitle non-medical referrers to identify aspects and referral criteria within a pathway have become well-established in most cases.

Practical solutions to problems
In last year’s report we gave examples of how organisations identified appropriate local solutions to common errors, including reminding referrers of their responsibilities for providing adequate information on the referral to allow it to be justified, and using local newsletters to communicate the same messages. Here are some more from 2010.
Raising awareness of radiology staff
One trust told us how it raises awareness internally of the different types of error in an annual internal report to staff in the radiology department. Using its own categories, it identified errors that were required to be reported to CQC, broken down by modality. Another trust put up notices on boards in areas for radiology staff to communicate learning points for radiation incidents as part of its strategy to minimise the chances of a repeat error.

Arrangements for referrers
A number of organisations have struggled to develop responses to errors made by referrers. Some have identified this to be mainly a problem with new intakes of trainee medical staff (FY1, FY2) and have refined their induction course to reflect responsibilities of referrers, making them aware of this legal framework. This included awareness of the importance of providing sufficient, accurate clinical details of the correct patient to avoid errors, delays in diagnosis and the subsequent investigation activities, and how to retract a request before the examination has begun. Some organisations require staff to undergo this training in order for them to be entitled to make radiology referrals.

We have seen a variety of responses to persistent errors made by individual referrers, including:

- A strongly-worded reminder from the chief executive.
- Routinely notifying the consultant in charge of errant trust referrers.
- Returning the incorrectly filled out request card, asking the referrer to discuss the issue with his team to ensure that the correct patient details were entered onto the requesting system.

One organisation organised a local campaign to reduce referrer errors and improve induction processes, and looked at using screensavers to improve awareness of radiation protection, and challenge referrers with randomised ‘pop-ups’:

- ‘This examination is the equivalent of 400 CXR, do you really need to do it?’
- ‘Have you double-checked it is for the correct patient?’

Radiology administration/clerical errors
An issue that continues to feature in notifications relates to errors made by administration and clerical staff that have resulted in errors involving the wrong patient, wrong modality or wrong laterality. These were not subsequently detected by colleague radiographers or in the scheduling of female patients for specific high-dose examinations. Most radiology departments have procedures to ensure that clinical or medical colleagues carry out checks for previous examination (to guard against an inadvertent repeat) or to check the original request form (even if scanned into RIS) to ensure that the correct, original request has been generated on the correct patient in the invitation letter that admin and clerical staff generate.

We have noted from notifications in 2010 that admin and clerical staff have:

- Incorrectly identified the patient, and have inadvertently made an appointment for another patient.
• Misread information on the hand-written request, inviting patients for the wrong examination.
• Made a booking error of a patient onto the computerised radiology information system.

Other operator errors have led to the incorrect filing of digital X-rays or nuclear medicine images into wrong patient folders, prompting unnecessary subsequent examinations and emotional concerns as well as delays in the examination of the intended patient.

**Ward arrangements**
A number of notifications have been initiated due to a lack of clarity concerning arrangements on the wards, leading to the wrong patient being taken to X-ray and inadequate identification checks being carried out before an X-ray. Some strategies to ensure that the correct patient gets the X-ray include:

• Ward staff identifying patients that need an X-ray at shift handover meetings.
• Ensuring wristbands are legible.
• Porters checking with the staff nurse that they have the correct patient.
• Ensuring arrangements are in place to identify patients with similar names.
• Doctors filling in requests at the patient’s bedside.

One of the more notable errors involved a simple chest X-ray carried out on the wrong inpatient on a ward, who was brought to X-ray by a porter and student nurse. The established ID procedures were not followed. On discovering significant pathology, the patient was referred the next day for high-resolution CT of the chest. However, when this was carried out, it did not show any pathology. It became clear that these examinations had been carried out on different patients, and the trust attempted to follow up the error by trying to identify which patient had attended for the chest X-ray. Unfortunately, their first attempt at identifying the most likely patient was incorrect and another patient underwent an unnecessary chest X-ray. Clearly the ID procedure should be followed at all times to avoid unnecessary follow-up effort involving re-sorting correct images into correct patient folders, trying to remember which patient attended the original X-ray, and taking witness statements.

**Nuclear medicine**

**Referrer errors and ‘bone scans’**
Some errors occur where nuclear medicine bone scans have been performed when the referrer meant to request a DEXA bone densitometry scan, MRI scan or even a CT scan. Sometimes there may be little in the clinical detail that would alert clinical or medical staff to the error, and the request is duly authorised and performed. Clearly, the request should be specific to the type of examination requested and practitioners and operators should always be alert to the possibility of misdirected or mistaken referrals. Some departments use ‘modality’ colour-coding of paper request cards and this type of error is probably less common in electronic requesting systems. Another measure is to remind doctors at induction of the potential confusion and the need for accuracy, and to include
the modality when requesting ‘scans’. Administrative and clerical staff may also be involved in misreading or misdirecting requests; these staff should also be aware of the different types of scans being requested.

**Wrong radiopharmaceutical**

The number of instances of the wrong radiopharmaceutical or activity being administered is fortunately very small at any one department or across the nuclear medicine community generally. However, they do constitute a significant number of the nuclear medicine notifications. When they do occur, poor practice is involved somewhere in the storage, dispensing, handling and labelling of vials and syringes, contrary to procedures in place. It seems clear that safe practice should involve making sure that administrations are labelled and brought from storage as required, rather than having several syringes or unlabelled administrations in the patient area at the same time. It is also essential to make a final check of a patient’s identity and intended examination on the request form, against the radiopharmaceutical and activity actually selected, immediately before the administration.

**Exposure in pregnancy**

It is reassuring that, to date, notifications of the unintended irradiation of a foetus during nuclear medicine examination or treatment have always been because pregnancy was ‘unknown’ and that there had been no breakdown in the pregnancy procedure or practice. Nevertheless, because of the potential risks involved, especially in nuclear medicine therapy, one department took the opportunity to strengthen its procedure and the information provided to patients to ensure that the risks were recognised by all concerned. As there is such a variation of practice around the nature of the pregnancy check, which may include a pregnancy test, we hope that the professional bodies can develop guidance in this area.

**Radiotherapy**

**Treatment errors including geographical misses and missed moves**

Treatment errors, particularly geographical misses, comprise the most common type of notifications arising from incidents in radiotherapy. They typically arise from the failure to perform field movements as specified in the treatment plan and set-up instructions. Sometimes fields are aligned with the wrong tattoo or reference plane, or the wrong focal skin distance (FSD) is used. Upon finding that they have reported more than one or two similar errors over the year, some organisations rightly look for underlying trends and causes. The “error of the month” in *Safer Radiotherapy*, published by the HPA, provides useful guidance in aiming to reduce the likelihood of such mistakes.

**Competencies, entitlement and skill mix**

From our experience of carrying out inspections of clinical departments and following investigations, we have formed the view that, in general, radiotherapy departments ensured that operators are trained for the tasks they undertake and a ‘competency’ matrix was generally available describing what tasks that individual staff were entitled to perform, whether in simulation, planning, treatment, or verification. In just a few notifications, organisations admitted that the root cause of the incident was a lack of trained and competent staff, perhaps because of staff shortages or particularly unusual circumstances. The situation may be more difficult when the treatment is rare or unusual and there is the challenge of trying to ensure existing competencies are kept up
to date while supervision and training are extended to newer or rarer tasks. Overall, we expect to see evidence that departments have arrangements and processes in place to manage the day-to-day staffing, skill mix and supervision requirements within the overall training, competency and entitlement framework.

**Queuing of patients and plans**
Although patient identity errors occur very rarely in radiotherapy, we have received several notifications where a patient has been treated with the plan intended for another patient. This may occur when ‘queuing’ of patients and plans become displaced or are changed to reflect transfer of patients between machines or their treatment times. We regard these incidents as high risk, but fortunately the potential near-miss is only likely to result in an actual treatment or planning error when the ‘wrong’ treatment or plan is very similar to that expected for the patient on the couch. It is essential that the check of patient identity against intended treatment plan and prescription is performed concurrently, or without interruption which could lead to error, immediately before starting treatment.

**Incidents in referral and authorisation**
Some of the potentially high risk errors in radiotherapy arise directly from the referral and prescription process. There is a balance between the requirement to start treatment as soon as possible against the need for accurate or complete source data. We have seen several instances where treatment has been authorised and commenced in the expectation of positive radiology or pathology, only for none to be found and no disease was present or it was in a different site. Specification of source clinical data, or ‘referral criteria’ under IR(ME)R is required before the authorisation and decision to treat, and should be an essential part of the treatment protocol. We are aware that, alternatively, if the treatment is ‘off-protocol’, then separate arrangements and procedures will apply.

During 2010, we saw how one disease site in a patient was not treated because the radiology report from a different organisation, on which treatment was based, was incomplete. Elsewhere, we were notified of an error in the timing of whole brain prophylactic cranial irradiation, authorised by the consultant, that should have commenced several weeks after completing chemotherapy treatment, but in fact commenced earlier, with serious consequences. We note from this and several other incidents that authorisation of plans and completion of prescription by the clinical oncologist should always be made with the plan, patient referral and file notes at hand, particularly when the clinical oncologist may not be familiar with that patient’s case.

**Oversight of serious untoward incidents**
In a previous quarterly report we noted that two tertiary radiotherapy centres had arrangements to provide clinical support at meetings investigating exposures and serious untoward incidents (SUIs). This might be a suitable model for all radiotherapy errors and from clinical disciplines that might benefit from external oversight of a SUI.
How to contact us

Phone: 03000 616161
Email: enquiries@cqc.org.uk
Web: www.cqc.org.uk

Write to us at:
Care Quality Commission
National Correspondence
Citygate
Gallowgate
Newcastle upon Tyne
NE1 4PA

Please contact us if you would like a summary of this publication in other formats or languages.

Registered office:
Care Quality Commission
Finsbury Tower
103–105 Bunhill Row
London
EC1Y 8TG