Inspecting Informing Improving

Healthcare Commission

Ionising Radiation (Medical Exposure) Regulations 2000

A report on regulation activity from 1 November 2006 to 31 December 2007

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Summary

The medical use of ionising radiation in radiotherapy treatment or diagnostic procedures is a vital part of healthcare provision. Used appropriately, it has life-saving potential. However, when errors occur they cause distress and, in extreme cases, have the potential to cause harm.

A core principle of our work is the use of information to improve patient safety. This report highlights trends from analysis of incidents where patients have received a dose of ionising radiation 'much greater than intended'. In our future inspection activities, we will look at how healthcare providers use the learning from these incidents to improve patient safety.

The Department of Health estimates that in the NHS in England, 25 million diagnostic imaging examinations involving ionising radiation are carried out each year. This figure is higher still when examinations carried out in the independent sector and exposures to ionising radiation for radiotherapy treatment are included.

In 2006, the UK Government introduced legislation that transferred responsibility for regulating the medical use of ionising radiation in England from the Department of Health to the Healthcare Commission. This move aligned the regulatory approach to this aspect of healthcare with the wider responsibilities of the Commission.

The Healthcare Commission adopts a proportionate risk-based approach to regulation. In developing our programme of work in this area, we have used external expertise from other regulators and professional bodies to inform our priorities for inspection activities. We aim to integrate these activities with our existing methodology for assessing the performance of healthcare providers, while developing expertise to establish the cause of serious incidents.

This is the first full report to be published since the Ionising Radiation (Medical Exposure) Regulations came into force in 2000. It highlights the nature of incidents where patients have been exposed to ionising radiation to a degree 'much greater than intended'.

The total number of notifications we received during the 14-month period from 1 November 2006 to 31 December 2007 was 329. In the overall context of the number of exposures in the NHS, the number of notifications is small, amounting to 1 in every 88,000 procedures carried out. However, behind each of the 329 notifications, there is a patient who has been affected because of a failure in medical procedures. In the vast majority of cases they will have suffered little or no long-term impact on their health, but these are mistakes that could and should be avoided.

As we develop our future activities, while continuing to react to serious incidents, we will also focus on those providers that have not reported any incidents within the past 14 months. This is to identify if this lack of reporting is a result of strong internal procedures that have prevented errors, or if it is an indicator of failure in reporting and governance procedures.

The key findings and recommendations in this report are:

- The total number of notifications we received during the 14-month period from 1 November 2006 to 31 December 2007 was 329.
- The biggest cause of unnecessary x-ray examinations (44% of the 240 diagnostic examinations) was incorrect patient identification.
- The majority of such unintended exposures are of a low dose and carry very little additional risk to individual patients.
- The Commission's inspection programme of radiotherapy departments has shown good overall compliance with regulations.
- Hospitals should seek to introduce measures to minimise the recurrence of referring the wrong patient, such as issuing reminders to key referring staff, and encourage radiography staff, wherever practicable, to correlate information on the request form with symptoms presented by the patient.
- We will continue to work with organisations such as the Royal College of Radiologists and the National Patient Safety Agency to disseminate safety information and develop guidance in areas of mutual interest.

Introduction

The Ionising Radiation (Medical Exposure) Regulations 2000 (IR[ME]R)[1] came into force on 1 January 2001. The regulations are intended to:

- Protect patients from unintended, excessive or incorrect exposure to radiation.
- Ensure that, in each case, the risk from exposure is assessed against the clinical benefit.
- Ensure that patients receive no more exposure than is necessary to achieve the desired benefit within the limits of current technology.
- Protect volunteers in medical or biomedical, diagnostic or therapeutic research programmes and those undergoing medico-legal exposures (such as those required for employment or emigration purposes).

In early 2006, the Department of Health consulted on proposed amendments to the regulations, which included transferring responsibility in England for their enforcement, including provisions for inspection, from the Department of Health to the Healthcare Commission. This resulted in the Ionising Radiation (Medical Exposure) (Amendment) Regulations 2006, which came into force on 1 November 2006. From this point, we started to enforce the regulations through a programme of assessment and inspection. The regulations also require employers to notify us if a patient is exposed to ionising radiation to an extent that is "much greater than intended".

Notifications of exposures much greater than intended

An important aspect of the regulations relates to the reporting of incidents of radiation exposure that may have affected patients. Regulation 4(5) states that:

> "Where the employer knows or has reason to believe that an incident has or may have occurred in which a person, while undergoing a medical exposure was, otherwise than as a result of a malfunction or defect in equipment, exposed to ionising radiation

[1] IR(ME)R implements EC Directive 97/43/Euratom. The regulations are made under the European Communities Act 1972 and are enforced as if they are health and safety regulations made under section 15 of the Health and Safety at Work Act 1974 (HSWA), breach of which is a criminal offence.

> to an extent much greater than intended, he shall make an immediate preliminary investigation of the incident and, unless that investigation shows beyond a reasonable doubt that no such overexposure has occurred, he shall forthwith notify the appropriate authority and make or arrange for a detailed investigation of the circumstances of their exposure and an assessment of the dose received."

Current guidance on what constitutes such an exposure appears on the Department of Health's website: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4007957.

As part of our ongoing responsibility for the regulations, we will:

- Identify, wherever possible, potential problems that could put patients' safety at risk.
- React quickly and appropriately to safety issues that emerge.
- Make the best use of information and intelligence.
- Build up a database of information.
- Focus our activities in high-risk areas, such as radiotherapy treatment, along with random samples in areas where there is less risk to the individual but a larger number of procedures conducted.
- Work with others in the sector, including professional and other regulatory bodies, over safety issues.
- Give information to the public and service providers to help improve safety.

This report provides an analysis of such notifications during our first 14 months of enforcement (for the period 1 November 2006 to 31 December 2007). We now intend to publish quarterly update reports.

Our first 14 months of activity

In December 2006, we organised workshops for our staff. Building on the expertise of the Department of Health, the Health Protection Agency, the Health and Safety Executive and professional bodies, these workshops shaped our inspection activities.

In July 2007, we appointed a specialist IR(ME)R inspector to lead all our inspection activities, assess the notifications and provide expert advice. We also nominated assessors and, with the help of the Health Protection Agency, trained them to provide local support for issues relating to IR(ME)R. The training included modules that are taught in the various specialised radiation areas within IR(ME)R.

In the first year, our priority was to develop a system for receiving, recording, reviewing and processing notifications of incidents. We piloted an online form to simplify the notification process and give speedy confirmation of receipt. In response to feedback from users, we added extra fields to the form to build up more comprehensive information.

We often need to gather additional information when assessing and processing notifications. Where the incident is high-risk and may have significant implications, we may inspect premises to investigate more fully. When we close the file on a notification, we inform the chief executive of the organisation and the individual who made the original notification. Files are only closed if we are assured that lessons have been learned and that the provider has taken remedial action if appropriate. We provide feedback on trends, best practice and areas of improvement to service providers and professional bodies.

To further refine the notification system, we invited the Department of Health to review the notifications received in the first three months and to compare the consistency of our triage process with that of its previous escalation methodology. They agreed with all of our decisions.

Our specialist staff were also supported by 'mentoring' from the Health Protection Agency, which provided assurance on the proposed action in relation to the 'higher risk' notifications where patients receiving radiotherapy treatment received an ionising radiation dose that was 'much greater than intended'.

Findings

In the first 14 months of regulation (from 1 November 2006 to 31 December 2007), we received 329 notifications of incidents. The average weekly number is just over five, compared to the three notifications per week typically received previously by the Department of Health. Although the reasons for this increase may be complex, it is possible that raised awareness of IR(ME)R associated with the transfer of responsibility for inspections to the Healthcare Commission, improved governance processes by employers, and the introduction of an online notification system may all have contributed.

By aligning our work on enforcing the regulations through a programme of assessment and inspection with the wider regulation of healthcare and our key priorities of improving patient safety, it reinforces the importance associated with the regulation of this aspect of healthcare.

Our analysis shows that the 329 notifications came from 107 institutions – nine from the independent sector, two from PCTs and the remainder from NHS acute trusts. As might be expected, some organisations have reported a number of incidents, while many other healthcare providers using ionising radiation have not yet notified us of a single incident. Given the large number of diagnostic procedures carried out by healthcare providers, we will focus some attention in the coming year on understanding why there is a variation in reporting. We are concerned that, despite the increase in notifications, there may be under-reporting in some areas due to the lack of robust incident identification, reporting or governance structures.

We are also concerned at the number of notifications involving the 'wrong' patient. This indicates a systems failure that has much broader implications for patient safety. We will work closely with professional bodies to identify what more can be done by providers to eradicate these errors.

Notifications by type

Ionising radiation is used widely for diagnosis and treatment in hospital radiology, nuclear medicine and radiotherapy departments, providing a general resource across all specialties. In radiology, the use of the CT scanner continues to expand and accounts for a significant proportion of all exposures. Diagnostic x-rays are also used in breast screening, dentistry, chiropractic and bone

densitometry. In specialised centres, x-rays are also increasingly being used for x-ray guided interventional radiology and cardiology procedures as an alternative to major surgery, and although they are extremely useful, individuals can be exposed to relatively high doses. There are over 50 radiotherapy centres in England using linear accelerators for x-ray megavoltage beam therapy and some also providing superficial x-ray and brachytherapy treatment service using sealed radioactive sources.

Ionising radiation has various uses that can be classified into three basic types:

- 'diagnostic x-ray'
- 'nuclear medicine' and
- 'radiotherapy'.

Nuclear medicine can also involve therapeutic administrations of radiopharmaceuticals as well as being used for diagnostic purposes. We have categorised the notifications received in the first 14 months into these basic types, shown in Table 1.

Table 1: Number of notifications by modality

Month	Diagnostic x-ray	Nuclear medicine	Radiotherapy	Total
November 2006	12	1	3	16
December 2006	14	1	7	22
January 2007	22	1	5	28
February 2007	18	3	3	24
March 2007	16	4	5	25
April 2007	18	3	1	22
May 2007	13	2	6	21
June 2007	16	1	6	23
July 2007	16	2	2	20
August 2007	12	0	4	16
September 2007	8	0	7	15
October 2007	34	2	7	43
November 2007	23	3	6	32
December 2007	18	0	4	22
Total (14 months)	**240**	**23**	**66**	**329**
Monthly average	17.14	1.64	4.71	23.50

The geographical spread of reporting across England is generally consistent. As we receive more notifications, we will analyse the geographic data more closely, to highlight where there is a good culture of incident-reporting. We will also inspect a random selection of services that have not reported any incidents, to determine whether zero notification is a sign of best practice in action, or reflects a poor culture of incident-reporting.

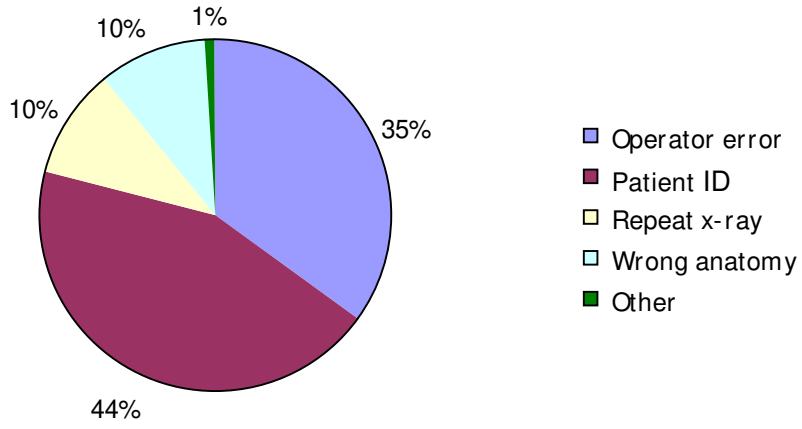
Part way through the reporting year we refined our data collection tool to improve the quality of information we receive, and subsequently feed back. This now includes an analysis of the type of notification. For example, in diagnostic radiology, we now report on whether plain film/CR/DR, CT-scanning, bone density scanning (DEXA), cardiology, interventional radiology, mammography, dental, or fluoroscopy is used.

Diagnostic x-ray notifications

In the first 14 months, we received 240 diagnostic x-ray notifications – mostly from hospital x-ray departments, amounting to 73% of the total. Most of these related to simple radiographic exposures and were generally of low dose and low risk. However, approximately a third involved CT scanning, where doses are at the upper end of the spectrum in diagnostic radiology.

Interventional radiology and cardiology represent some of the very highest doses within diagnostic x-rays and continue to provide an alternative to surgery. We did not receive any notifications of these types of exposure.

Figure 1: Diagnostic x-ray notifications by type of error



The type of incidents varied widely, but the most frequent cause of failure was carrying out an x-ray on the wrong patient. (This is discussed again later in this report). As shown in Figure 1, other notifications arose from imaging the wrong part of the body, from errors by the operator in performing the exposure and from imaging procedures being unnecessarily repeated. Clerical or booking errors account for some notifications, in particular those involving duplicate request forms, films incorrectly filed or labelled, or the wrong set of patient demographic labels filed inside a patient's notes.

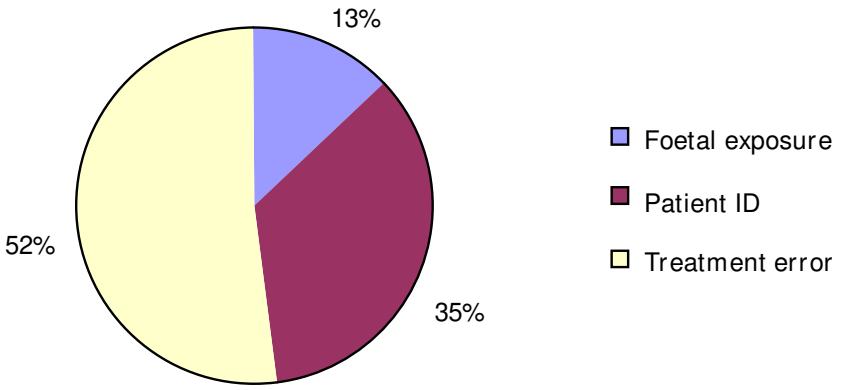
As a part of the follow up to each of these incidents trusts showed us what action they are taking to reduce the likelihood of similar incidents occurring again. Through engagement with professional bodies, we will seek to ensure that the wider learning reduces the risk of similar incidents occurring elsewhere.

Data collected by the Department of Health suggest that the NHS carries out approximately 25 million diagnostic imaging examinations involving ionising radiation each year, in addition to those carried out in the independent sector. This figure is even higher when dental examinations are included. Therefore, the vast majority of exposures are performed without incident. In the overall context of the number of exposures carried out in the NHS, the number of notifications is small, amounting to 1 in every 88,000 procedures carried out.

Nuclear medicine notifications

We received 23 notifications relating to nuclear medicine in our first 14 months of regulation, the vast majority of which were from diagnostic nuclear medicine investigations. As figure 2 shows, approximately a third arose from patient identification errors – a smaller proportion than for diagnostic x-rays. Half of the notifications involved performing the wrong examination, for example, carrying out the wrong type of test or administering the wrong radiopharmaceutical to the patient, or carrying out a bone mineral density scan instead of a bone scan. We received three notifications following administration of radiopharmaceuticals to patients who did not declare a pregnancy. Two of these involved therapeutic administrations of Iodine-131.

Figure 2: Nuclear medicine notifications by type of error



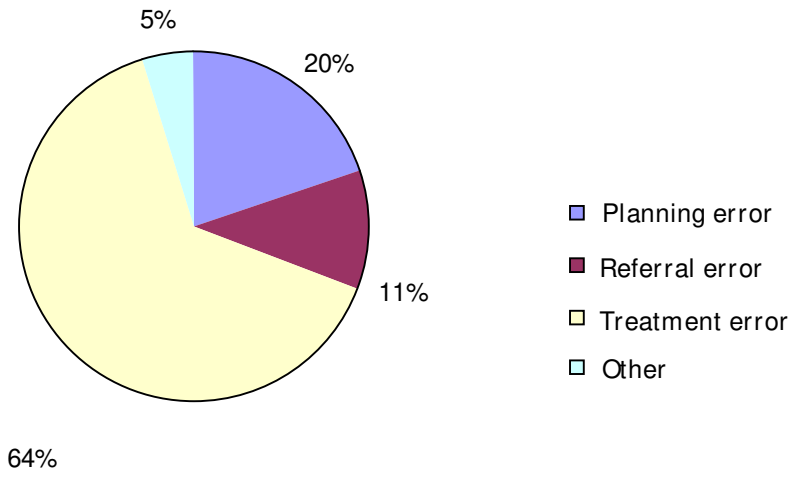
Radiotherapy notifications

We received 66 notifications from radiotherapy departments in England. To date, around half of the organisations providing a radiotherapy service have notified us of exposures under Regulation 4(5).

Of the 66 notifications, almost two-thirds (64%) involved a treatment error. Of these, approximately a third involved a geographic miss of one fraction only during a course of treatment, with a smaller proportion involving the delivery of more than one fraction to the wrong part of the body or at the wrong fractionation rate. Errors happened when staff in pre-treatment imaging did not record machine or couch movements correctly or did not write down correct instructions for colleagues. In other cases, treatment staff did not interpret the setting-up instructions correctly or used incorrect positioning marks on the patient from which to position them with the treatment beam. In some notifications, operators omitted to fit shielding designed to safeguard critical organs. A small number of notifications involved errors in prescribing of the patient's dose and fractionation. Three notifications related to pre-treatment imaging or 'planning' exposures in radiotherapy.

For each of these incidents the providers concerned have reviewed procedures and put in place actions that should prevent similar events from occurring in the future. Through engagement with the Royal College of Radiologists, we will use the learning from these incidents to reduce the risk of similar errors occurring elsewhere.

Figure 3: Radiotherapy notifications by type of error

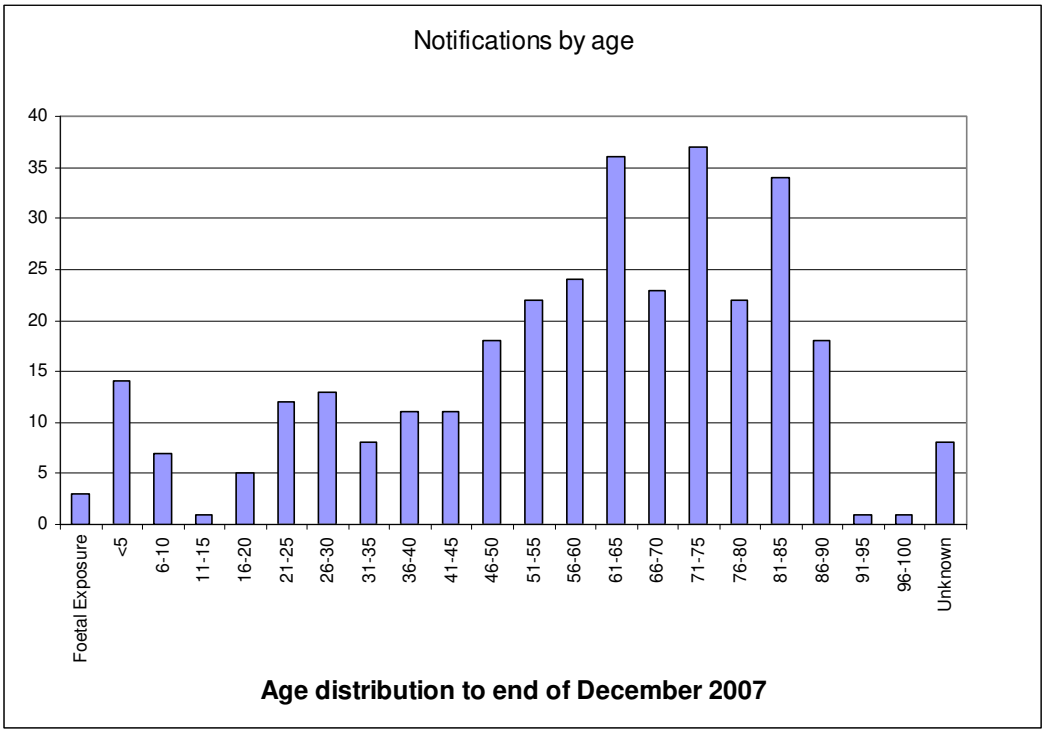


Notifications by age of patient

The range of notifications grouped by the age of patients is broadly as expected, reflecting typical ages of patients attending for radiological examination (see Figure 4). We will use this, together with new data being collected, as a baseline to review any changing trends over time.

Notifications involving children will remain of particular concern. We received a small number of notifications of foetal exposures where a woman, unknowingly pregnant, had undergone radiological investigation. We have not established any actual failures in IR(ME)R procedures or practice relating to these unintended exposures.

Figure 4: Notifications by age of patient



Patient identification issues

Identification of patients is recognised as a cornerstone of patient safety and is embedded in the requirements for employers' written procedures in Regulation 4(1), Schedule 1(a). This issue was recognised in 1995 in the publication *Health Service Guidelines 95(3) Health Service Use of Ionising Radiations*. However, failures in patient identification accounted for almost half of all notifications from diagnostic x-ray and nuclear medicine. These are often mistakes made by the referrer who attaches the wrong patient identification label to the x-ray request form. Sometimes this can occur using computer-based x-ray request systems, where a clinician inadvertently selects the wrong patient for examination.

Subsequently the operator in the radiology or nuclear medicine department, who is responsible for carrying out a final identity check before the exposure, may not discover the mistake unless the clinical detail on the request is at variance with symptoms presented by the patient who arrives for examination.

Other unintended exposures have occurred when the wrong patient presents for examination and the operator performing the final identity check fails to follow the employer's written IR(ME)R procedures, which normally require a three-point check of date of birth and address in addition to asking the patient to give their full name.

Sometimes, the wrong inpatient may be collected from the ward and taken to the x-ray department because of inadequate checks made between nursing staff and porters. These errors can be compounded when patients have identical or similar names. However, they should be detected by complete three-point checks, or checks of wristbands made in the radiology department.

Identification errors made on vulnerable patients are of particular concern. These include children, older people, confused patients, and patients whose first language is not English. We will continue to closely monitor trends in such errors and use these as part of risk profiling for inspections.

Inspection, joint working and communication

Proactive IR(ME)R inspections and assessments

We aim to regulate and enforce IR(ME)R through a programme of assessment and inspection. We have developed inspection and decision tools to support the proactive assessment of all radiotherapy centres, which will be assessed twice over a five-year period from April 2007. Between July and the end of December 2007, we carried out 15 such inspections. This approach to inspecting radiotherapy departments is consistent with the comments made by the Chief Medical Officer in his 2006 Annual Report on the use of radiotherapy in the treatment of cancer and the need for it to be delivered safely to ensure that risk is minimised.

Future inspections will also include a random selection of other radiological practices, drawn from areas such as diagnostic radiology, dentistry, nuclear medicine, chiropractic and cardiology. The inspection methodology is in line with the Healthcare Commission's overall work and will be targeted and risk-based. We have emphasised the importance of risk-based and responsive assessments, which is part of a long-term strategy on intelligent regulation. This direction is in line with the work of many other regulators and the recommendations of the Better Regulation Task Force.

An additional aim is to map and continue to integrate key findings from IR(ME)R inspections into our broader assessments, including the annual health check. Reports on all proactive inspections will be published on our website.

Reactive IR(ME)R inspections and assessments

The lead or specialist associate IR(ME)R inspector reviews all notifications made under Regulation 4(5) and triages them according to the risk presented to individual patients. The majority of these notifications are low risk and result in little or no long-term harm to the patient.

However, one possible outcome of the assessment process is the need to visit premises to gather more information about the incident. We may need to take witness statements from the individuals involved, or, in more extreme cases, interview witnesses under caution. One such reactive inspection took place in the first year, which concerned the complete geographical miss of the intended target of a patient undergoing radiotherapy treatment.

We have a duty to safeguard the public by acting swiftly and appropriately to complaints, concerns and significant failings in the provision of healthcare. We have received one complaint concerning poor radiological practice, and we are currently gathering evidence to assess if regulatory action is required.

Communications with other bodies

The NHS chief executive's bulletin from the Department of Health (Issue 345, 17-23 November 2006) informed all NHS providers that we had taken over enforcement responsibility for the regulations. We also wrote to independent healthcare providers with a questionnaire to gather information on where radiation is being used in the independent sector, as this information was not available when responsibility was transferred to the Healthcare Commission.

We initiated an engagement programme with professional organisations to raise awareness of IR(ME)R, not just in the higher risk areas, but also in those areas perceived to be low risk/high volume, such as chiropractors or dentists.

Our meetings with professional bodies and other stakeholders have already helped to identify areas where there is common ground and opportunities for joint working, for example in developing professional guidance in radiotherapy. We have also held discussions with the Health and Safety Executive in relation to possible future joint inspections of radiation healthcare facilities and have met with regulators of medical radiation (including those with IRMER responsibilities outside England). We are presenting the Commission's IR(ME)R programme and ways of working at meetings of NHS trusts and we also presented at the 2007 UK Radiology Congress.

The Royal College of Radiologists is developing an accreditation programme for radiology departments and we will work with them to ensure that learning from incidents influences the development of best practice.

This 14-month report is the start of a wider communication strategy and will be followed by quarterly updates on our website, aimed at sharing the learning from this regulatory activity. We will produce a further report in early 2009 to cover the analysis of notifications and proactive engagements during 2008.

Summary of progress

Our review of the first 14 months shows that the transition has been successfully completed. In particular we can identify key milestones achieved:

- Since the transfer of responsibility on 1 November 2006, we have introduced an externally-ratified process for notification and escalation of incidents.
- We have trained the assessors and appointed a lead IR(ME)R inspector.
- We have revised the web-based notification form to reflect comments from healthcare providers and professional bodies.
- We have implemented the escalation process successfully and carried out one reactive inspection.
- We are using specialist analysts to target inspection activities and identify trends in notifications.
- We have identified patient identification errors as a cause for concern and will continue to monitor these.
- We have developed decision and inspection tools for the programme of proactive inspection of high-risk areas such as radiotherapy and we plan to publish an overall summary picture of compliance against IR(ME)R.
- We are investigating a complaint concerning poor radiological practice.
- We have developed relationships with professional bodies and other regulatory agencies and identified potential areas of joint working.

Next steps

- We will continue to enforce IR(ME)R through an efficient programme of intelligent assessment and inspection that is in keeping with the wider strategy and methodology of the Healthcare Commission.
- We will extend the programme of proactive inspection and assessment to a sample of other radiological practices and develop appropriate lines of enquiry.
- We will ensure that our response to notifications continues to be timely and proportionate and that we make effective use of accumulated data.
- We will report annually and publish our outcomes quarterly, on the safety pages on our website, to share learning and improve patient safety.

- We will continue to work in collaboration with professional organisations with active interests in the field of medical radiation.
- We will work with the National Patient Safety Agency, the Health Protection Agency and other relevant parties to conduct an analysis of serious incidents in radiotherapy, to identify common causes and the scope for reducing risk.

This publication is available in other formats and languages on request. Please telephone 0845 601 3012.

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