Quarterly update report on regulatory activities for
IR(ME)R 2000
1 January to 31 March 2008

In March 2008, we published a report on our activities in enforcing the Ionising Radiation (Medical Exposure) Regulations 2000. The report included an analysis of notifications of incidents for the period 1 November 2006 to 31 December 2007, where patients had received an exposure of ionising radiation to an extent 'much greater than intended'. The 14-month report is available on our website at: www.healthcarecommission.org.uk/_db/_documents/IRMER_14month_report.pdf

This is the first of our quarterly follow-up reports and covers the period 1 January to 31 March 2008.

Overview of activities

In this quarter:

• We completed seven proactive inspections of radiotherapy departments, taking the total number of inspections carried out in the year to March 2008 to 22. One inspection during this quarter was in the independent healthcare sector.

• We received 79 notifications of exposures 'much greater than intended' and completed follow-up activity on 73 notifications (more information on the notifications received in each of the three disciplines is given below).

• We presented the Commission’s activities and findings in our first year of regulation at an IR(ME)R update meeting organised by the Chief Scientific Advisor for the Welsh Assembly Government. The meeting was entitled ‘Safety in Imaging and Radiotherapy’ and delegates included radiation healthcare professionals.

• We held a number of meetings with those interested or responsible for radiation protection. These included representatives from the Department of Health, the National Patient Safety Agency, the Royal College of Radiologists, the Society and College of Radiographers, the Health Protection Agency, the General Chiropractic Council and the General Dental Council.

• We continued to enhance the skills of our IR(ME)R inspection team, and two staff undertook training in ‘Law, Evidence, Procedure and Best Practice’ and in ‘Advanced Investigative Practice’.
Key findings

1. Our proactive inspections of radiotherapy departments have shown:
   - Some uncertainties in the line of accountability from the IR(ME)R written procedure, often found within the radiotherapy quality assurance system (QART), to the employer. In addition, there are challenges in fully integrating and cross-referencing IR(ME)R employers’ procedures against relevant work instructions into the QART system.
   - Inconsistent recording of the training of clinical oncologist operators in practical tasks such as outlining target volumes on CT scans.
   - An incomplete understanding across radiotherapy departments of patients’ doses arising from imaging exposures.

2. Analysis of the notifications shows the difficulties that organisations continue to face in managing patient identification as part of the medical exposure process. ‘Referrer errors’ represent a large proportion of the notifications.

3. There are delays in the time taken to notify us of exposures ‘much greater than intended’ under regulation 4(5). Figure 1 shows the variation in the time taken to report incidents. The regulations require organisations to make “an immediate preliminary investigation” and “unless that investigation shows beyond a reasonable doubt that no such exposure has occurred, shall forthwith notify the appropriate authority”. We expect notifications of such exposures to be timely and made as soon as practicable after the preliminary investigation.

4. We remain concerned about the variation in the rates of reporting exposures ‘much greater than intended’ across the country in both the NHS and the independent sector. We will use details from notifications, or the lack of them, to determine the priorities for carrying out inspections in the coming year.
Notifications received from 1 January to 31 March 2008

Across the three major disciplines, the total number of notifications in this quarter was consistent with previous levels. On average, we continue to receive five notifications a week. The breakdown of the 79 notifications is shown below.

Figure 2: Notifications received in quarter 1, 2008
Radiotherapy notifications

We received 20 notifications from radiotherapy departments in this first quarter. They all involved external beam treatments and were divided evenly between radical and palliative treatments. Apart from two notifications where the error occurred at the referral stage of the radiotherapy process, the other notifications were divided equally between mistakes that occurred in the planning of the treatment and those that arose in setting up the machine at the time of treatment.

Radiotherapy is a complex multidisciplinary process, and there are still challenges in making ‘checking’ systems more dependable. We will continue to focus on this area during our proactive inspection programme.

Figure 3: Radiotherapy notifications by type of treatment

Figure 4: Radiotherapy notifications by type of error
Diagnostic radiology

We received 52 notifications of exposures ‘much greater than intended’ in diagnostic radiology, with more than 40% arising from the use of computed tomography (CT) scans and the remainder mostly involving plain film radiography, including CR and DR scanning.

The majority of errors involved the identification of patients. Sixteen notifications resulted from ‘referral errors’, where the wrong patient was referred (by using the wrong demographic label for patients, or selecting the wrong patient from a drop-down menu) and a further 23 notifications were the result of ‘operator errors’, where the operator had not followed the well-established three-point patient identification check asking patients to confirm their name, address and date of birth. One trust has adopted a new approach to referring patients during ward rounds, which requires doctors to fill out the imaging request form at the patient’s bedside rather than at the end of the ward round, to avoid confusion about which test to carry out for which patient.

Although the number of patient identification errors is very small in relation to the number of examinations, it is clear that with increased awareness and/or small changes in working practice, the number of incidents can be reduced within existing resources.

It is interesting to note that we have not yet received any notifications relating to dental, interventional or cardiac procedures. We plan to gain further assurance in this area during our future assessment and inspection programmes.

Figure 5: Diagnostic radiology notifications by type of exposure

Figure 6: Diagnostic radiology notifications by type of error
Nuclear medicine

In the first quarter, we received seven notifications – five from diagnostic nuclear medicine and two from therapeutic administrations. The majority were due to operator errors resulting in the wrong patient being administered with radioactivity, or an incorrect radiopharmaceutical being administered to the intended patient.

Two notifications related to exposure during pregnancy, where the patients had confirmed that they were not pregnant at the time of the examination, but subsequently discovered that they were in the early stages of pregnancy when they were examined. The nuclear medicine staff had asked questions concerning pregnancy status and there had been no breakdown in IR(ME)R procedure or practice.

A potentially serious notification involved therapeutic administration of radioactive iodine, where a patient received the wrong capsule and incorrect level of radioactivity. Following a review of practice and procedures, the trust made a series of improvements including additional labelling and independent checks of the intended dose. We recommend that other healthcare providers using nuclear medicine adopt a review of procedures to avoid similar errors.

Figure 7: Nuclear medicine notifications by type of treatment

Figure 8: Nuclear medicine notifications by type of error
Next steps

We will continue to engage with stakeholders and with healthcare professionals at meetings and conferences to ensure that we share with them any key messages, main concerns and the learning from our work, in order to safeguard the patient, ensure that medical exposures are justified/optimised and to help reduce the frequency of exposures much greater than intended.

We will be developing priorities for inspections in the coming year, including clinical areas outside of radiotherapy, as well as developing the use of self-assessments as an alternative to traditional face-to-face inspections.