Inspection report

Inspection of compliance with the Ionising Radiation (Medical Exposure) Regulations 2000:

University Hospitals Coventry and Warwickshire NHS Trust

Date of inspection: 21 October 2008
Date of publication: August 2009
Report of inspection of compliance with the Ionising Radiation (Medical Exposure) Regulations 2000

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<td>Site inspected:</td>
<td>Walsgrave Hospital</td>
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About the Care Quality Commission

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

Whether services are provided by the NHS, local authorities, private companies or voluntary organisations, we make sure that people get better care. We do this by:

- Driving improvement across health and adult social care.
- Putting people first and championing their rights.
- Acting swiftly to remedy bad practice.
- Gathering and using knowledge and expertise, and working with others.

Introduction - enforcing the regulations

The Care Quality Commission assesses compliance with the Ionising Radiation (Medical Exposure) Regulations 2000, known as IR(ME)R as amended in 2006. The responsibility for enforcing the regulations transferred from the Healthcare Commission to the Care Quality Commission on 1 April 2009.

The regulations are intended to:

- Protect patients from unintended, excessive or incorrect exposure to radiation and ensure that, in each case, the risk from exposure is assessed against the clinical benefit.
- To ensure that patients receive no more exposure than is necessary to achieve the desired benefit within the limits of current technology.
- To protect volunteers in medical or biomedical, diagnostic or therapeutic research programmes and those undergoing medico-legal exposures.

Our inspection sought information from interviews and observations within the clinical settings, which are supplemented by documentary evidence, where appropriate.

This is a summary report of the findings from our inspection of the radiotherapy department, using information from the observations, interviews and documents collected. During the inspection, we recorded a summary of the evidence relating to the regulations.
Background to the inspection

The University Hospitals Coventry and Warwickshire NHS Trust provides a radiotherapy service to a population of approximately one million people from across the south of the West Midlands. It is part of the Arden Cancer Network and provides 3,400 new courses of radiotherapy each year from its new accommodation at the Walsgrave hospital. The centre comprises five linear accelerators, brachytherapy, a dedicated electron treatment machine, a conventional simulator and a CT-simulator, and treatment planning terminals across a dedicated radiotherapy record and verify network. Each of the five linear accelerators provides approximately 7,000 fractions of radiotherapy each year.

The centre comprised 13 whole time equivalent (WTE) clinical oncologists supported by two staff grades, one associate specialist, and four specialist registrars. In addition there were 40 WTE radiotherapy radiographers, 11 posts in radiotherapy physics and 13 additional staff in engineering and dosimetry, with no significant shortages compared with those recommended by respective professional groups.

The inspection

On 21 October 2008, the Healthcare Commission’s lead IR(ME)R inspector and another warranted IR(ME)R inspector visited the radiotherapy centre at Walsgrave hospital as part of a programme of proactive inspections of radiotherapy departments. This report is being published by the Care Quality Commission as the new regulator.

We addressed the entire patient journey, from referral for pre-treatment imaging through to the evaluation of treatment. The inspection was limited to the areas where patients would attend following a diagnosis of cancer and the subsequent decision to treat with high-energy radiation using a linear accelerator.

We also held a detailed discussion on risk management, including notifications made to the Commission of exposures ‘much greater than intended’, on other ‘near-misses’ not reported to the Commission, and on the trust’s response to the recommendations made following the Beatson Oncology incident in 2006.

We had received one notification from the radiotherapy department between November 2006 and the date of the inspection. It had been received shortly before the inspection had been announced. We used the inspection as an opportunity to make progress in our investigation into the circumstances leading to that exposure.
Summary of findings

The trust provided a copy of its IR(ME)R employer's procedures and associated work instructions in advance of the inspection. These, together with additional documentation seen during the inspection were detailed, comprehensive and included aspects of both radiotherapy and physics. The centre had organised its procedures and associated treatment protocols within an externally accredited quality management system. The cycle for reviewing documentation was noted to be three years rather than the two years recommended in professional guidance.

The procedures allocated clear responsibilities to duty-holders such as referrers, practitioners, and operators. During the inspection, we noted that there was a good understanding of the responsibilities of both the individual and of management under the regulations. The centre had employed a radiographer to manage the quality management system, and there was also a clinical oncologist in post with dedicated responsibilities for quality assurance.

The centre had ensured that practitioners and operators were adequately trained and we saw samples of training records for radiographers. We saw that staff had individual training portfolios, and managers kept relevant summary records of training. The training matrix was linked to competence assessment in both physics and radiography, but had yet to be extended to demonstrate records of entitlement and a link to the employer.

Medical physics experts were involved in radiotherapy as required by the regulations, and there was evidence of cooperation and team working between the various duty holders and the multi-disciplinary groups associated with beam therapy. Although some attention had been given to increasing the understanding of doses from planning exposures, this was reported as 'work in progress'.

Various measures were in place to record and minimise errors and near misses. We also saw that the centre had made a considered response following publication of professional guidance on radiotherapy errors, such as the Beatson Oncology report in 2006, *Towards Safer Radiotherapy*, and the more recent guidance on interpreting IR(ME)R in radiotherapy.

Areas of concern

There were no areas of serious concern during the inspection
Conclusions and recommendations

On the day of the inspection, the trust provided evidence which showed that the radiotherapy centre complied with IR(ME)R. The trust also provided us with assurance that it had procedures in place that were in line with regulatory requirements, and that risks were being managed within the centre’s governance structures.

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<th>Regulation</th>
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| Regulation 4: Duties of the employer | The trust should aim to conduct reviews of its employer’s written procedures every two years rather than the existing three years.  
The trust should revise its procedure for enquiring about the pregnancy status of patients, to include instructions for staff when a patient declares a potential pregnancy during treatment.  
The UHCW Trust Incident Management Policy, GOV-POL-005-07 should be revised to identify the Care Quality Commission as the organisation to whom the trust should make notifications regarding exposures ‘much greater than intended’. |
| Regulation 5: Duties of Practitioners, Operators and Referrers | The trust should ensure that relevant staff understand the potential detrimental effects of planning exposures. |
| Regulation 11: Training | The trust should continue to develop a clear strategy for the entitlement of operators, in conjunction with training and competency frameworks, which includes dates for this entitlement in radiography and radiotherapy physics. |