Ionising Radiation (Medical Exposure) Regulations 2000 - inspection report:

University Hospital of North Staffordshire NHS Trust

November 2008
Enforcing the regulations

The Healthcare 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 Department of Health to the Healthcare Commission on 1 November 2006.

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; and 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 North Staffordshire Hospital NHS Trust provides a radiotherapy, orthovoltage and brachytherapy service for a population of 845,000 from the North Staffordshire Royal Infirmary site in Stoke-on-Trent. It is part of the Greater Midlands Cancer Network.

The centre currently has three linear accelerators, a conventional simulator, a CT-simulator, treatment planning computer systems and associated networking. There are plans to build and fund a new radiotherapy centre with additional capacity for treatment and increased functionality, including the ability to provide image-guided radiation therapy, which is expected to be available in 2009. In terms of staff, the centre has six consultant clinical oncologist posts, 32 radiographer posts, and six whole time equivalent clinical scientist posts. According to the centre’s own analysis, there is a long-term vacancy for a clinical scientist and a significant shortfall in the number of staff in physics posts, compared to recommendations published by its professional organisation. The trust’s management has acknowledged this and arrangements are in place to increase these numbers before the move to the new centre.
Each year, the centre sees 2,000 new cancer patients for radiotherapy and chemotherapy services. Each of the three linear accelerators provides an annual workload in excess of 8,000 fractions.

The inspection

On 6 November 2007, the lead IR(ME)R inspector and an assessor from the Healthcare Commission inspected the radiotherapy centre at the North Staffordshire Royal Infirmary, as part of a programme of proactive inspections of radiotherapy departments.

We addressed the entire patient journey, from referral for pre-treatment imaging through to evaluation of treatment. The inspection was limited to areas where patients would attend following a diagnosis of cancer and the subsequent decision to treat using high energy radiation using a linear accelerator. We also held a detailed discussion on risk management regarding the trust’s response to ‘near misses’ and errors, and on its response to recommendations made following the Beatson Oncology incident in 2006.

The Commission had received no notifications from the radiotherapy department of exposures ‘much greater than intended’ between November 2006 and the time of the inspection. The decision to carry out an inspection at this trust was made independently of this analysis and was not prompted by the trust’s declarations in any other aspect of the Healthcare Commission’s assessment of Core Standards.

Summary of findings

The trust had provided in advance a copy of its IR(ME)R employer’s procedures, its departmental structure, sample work instructions from its quality management system and a copy of its radiation protection policy. The IR(ME)R procedures are included within the radiotherapy department’s quality management system. The procedures were complete and the staff delivering care ad treatment understood them.

Training records were kept up to date and linked to the entitlement of the various staff groups to practise in their respective roles.

The radiotherapy department follows procedures in the areas of clinical audit and risk management. It ensures that treatment plans are checked independently using a number of methods. The department has also developed a methodology to ensure that it considers issues using a multi-disciplinary team approach before new techniques are introduced and commissioned.

The trust has adopted an approach to patient identification which requires patients to bring with them their ‘Radiotherapy Passport’, a small yellow cardboard document that includes their demographics. This was reported to have worked successfully for several years without problem, though the risks inherent in such an approach had been discussed and recommendations made.
Areas of concern

We found no areas of serious concern during the inspection.

Conclusions and recommendations

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

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<tr>
<th>Regulation</th>
<th>Recommendations</th>
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<td>Regulation 4: Duties of Employer</td>
<td>We recommend that a dedicated post holder should maintain the employer’s procedures that are included in the centre’s quality management system. The department should review its patient identification procedure to include a photo of the patient. The department should update its procedure to notify the Commission of ‘exposures much greater than intended’ and the lists and signatures of duty-holders. The department should review procedures allowing family members to be involved in identifying patients. We recommend that the department considers displaying signage to remind female patients about the risks of becoming pregnant. The department should review its portfolio of treatments to include less common treatments, such as sarcomas.</td>
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<td>Regulation 5: Duties of the Practitioner, Operator and Referrer</td>
<td>The trust should reconsider the issue of entitlement of specialist registrars to act in the capacity of practitioner to be on behalf of the employer rather than consultants.</td>
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<td>Regulation 7: Optimisation</td>
<td>The department should continue to manage the risks inherent in the practice of manual data transcription, which were discussed and understood within the centre, before it relocates to the new centre in 2009.</td>
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