Ionising Radiation (Medical Exposure) Regulations 2000 - inspection report

Ipswich Hospital NHS Trust

August 2008
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.

The radiotherapy department at the Ipswich Hospital NHS Trust is located at the Heath Road site in purpose-built accommodation dating from 1991. It provides external beam radiotherapy and brachytherapy services to a population of more than 350,000 around Ipswich and East Suffolk.

The radiotherapy centre has three linear accelerator treatment machines, a simulator, treatment planning computer system and a dedicated radiotherapy record and verify network.

The department sees about 1,500 new cancer patients each year. The workload of each treatment machine is around 4,500 fractions annually. It has links into adjacent cancer networks and with other centres according to the type of tumour.
The inspection

On 14 August 2007, the Healthcare Commission’s lead IR(ME)R inspector, an associate specialist inspector, and an assessor inspected the radiotherapy department at Ipswich Hospital NHS Trust, 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 the evaluation of treatment. The inspection was limited to 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 in the context of the trust’s response to ‘near-misses’ not reported to the Commission, and its response to recommendations made following the Beatson Oncology incident in 2006.

Since 1 November 2006, we had received no notifications from the radiotherapy department of exposures ‘much greater than intended’. The inspection was not prompted by the trust’s declaration in this or any other aspect of our 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, and sample work instructions from its quality management system (QMS). The procedures allocated responsibilities to duty-holders, such as referrers, practitioners, and operators, and staff involved in the planning and delivery of treatment understood them.

The staff in the radiotherapy department showed an understanding of IR(ME)R requirements and there was an associated positive culture across the service. Good practice was evident in the attention to detail associated with the treatment of patients, safety and the avoidance of planning and treatment errors. Weekly multidisciplinary ‘planning’ meetings appeared to be an effective tool in helping this process. There was also evidence of an understanding of personal responsibilities under IR(ME)R among staff and of adequate training linking to entitlement to practice.

Although the employer’s written procedures were in place and integrated into an accredited QMS, some procedures did not appear to represent up-to-date working documents on which staff could rely. It was acknowledged within the department that some procedures and work instructions required review and possible revision. The loss of the radiotherapy quality manager two years previously and subsequent staffing difficulties meant that although the system was still being managed within the department, its recent development had suffered.

Areas of concern

We found 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 in the areas examined. It also provided the Commission with assurance that the trust had procedures in place that were in line with regulatory requirements and that risks were being managed within the centre’s governance structures.

This assurance was established by assessing the documentation provided in advance of the meeting, scrutinising procedures and work instructions during the inspection, and by discussing practice and procedures with clinical, scientific and medical staff.

We found the department to be compliant with the requirement for optimisation in relation to individually planned target volumes and sparing of non-target tissues. Work was apparent in the development of reference levels of dose for simulation and imaging exposures.

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<th>Regulation</th>
<th>Recommendations</th>
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<td>Regulation 4: Duties of employer</td>
<td>A number of IR(ME)R procedures were not up-to-date or did not reflect current practice. The department must continue to develop and integrate its IR(ME)R procedures, and ensure that they are kept up-to-date. In particular, development work is needed in some of the essential procedures identified in Schedule 1. The department should consider appointing staff with specific responsibilities in managing the quality management system to ensure that they can maintain the QMS and IR(ME)R procedures adequately.</td>
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<td>Regulation 11: Training</td>
<td>Training must be made available to medical staff for equipment and software upgrades alongside that of other professions, and documented accordingly.</td>
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