Inspecting Informing Improving

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

Hull and East Yorkshire Hospitals NHS Trust

January 2009
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 Hull and East Yorkshire Hospitals NHS Trust provides radiotherapy services to a population of approximately one million as part of the Humber and Yorkshire Coast Cancer Network. At the time of the inspection, the oncology centre was located at the Princess Royal Hospital, Hull, in the east of the city. The centre sees approximately 2,000 new cancer patients each year and its three linear accelerators perform an annual workload of 8,500 fractions per machine. The Princess Royal Hospital site also accommodates orthovoltage and brachytherapy treatment units, in addition to simulator and CT planning facilities. During 2008 the oncology centre was due to move into new purpose-built accommodation at the Castle Hill site in the west of the city. The department will expand to a facility with six linear accelerator bunkers.

In terms of staffing, the centre comprised 11 consultant clinical oncologist posts, with three specialist registrars and one staff grade oncologist. The specialist registrars rotate between the adjacent radiotherapy centres. There are 35.8 whole time equivalent (WTE) radiographer posts and 13 physics posts in place. A good proportion of the physics staff constitutes ‘pre-registration’ staff in training and there were 5.4 WTE dosimetrists in treatment planning. At the time of the inspection, there were three senior radiography
positions vacant and two unfilled posts in medical physics. It was reported that staff shortages and difficulties in recruitment, particularly at the more senior level, had adversely affected some areas of work, particularly the development of new radiotherapy techniques.

The inspection

On 4 March 2008, the Healthcare Commission’s warranted IR(ME)R inspector and an assessor inspected the radiotherapy centre at the Princess Royal Hospital, Salthouse Road, Hull, 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 from the oncology centre three notifications of exposures ‘much greater than intended’ between November 2006 and the time of the inspection. However, the decision to carry out an inspection at this trust was made independently of these, and it was not prompted by a declaration in any other aspect of the Commission’s assessment of Core Standards.

Summary of findings

The trust had provided in advance of the inspection a copy of relevant procedures. This included a departmental structure, various trust-wide radiation protection procedures and the trust’s policy and procedures on risk management and managing hazards. The documentation also included clinical oncology IR(ME)R procedures, relevant work instructions and forms, all integrated within an externally accredited quality management system. The procedures allocated clear responsibilities to duty-holders such as referrers, practitioners, and operators. Discussion of procedures and requirements under IR(ME)R indicated a good level of compliance. Although all aspects of IR(ME)R were covered by the procedures, it was agreed that improvements could be made in the integration and cross-referencing of IR(ME)R procedures and associated work instructions within the quality assurance system for radiotherapy (QART). It was noted that in a recent audit of the QART, the external accreditation body had recommended that management of the system should be improved.

The centre had ensured that practitioners and operators were adequately trained. Examination of a sample of records revealed how staff maintain their individual training portfolios, with managers having appropriate summary records of training. Training records were also observed to be linked to competence assessment, having been integrated into the knowledge and skills framework (KSF).

There was evidence of co-operation and team working in the centre between the various duty holders and the multi-disciplinary groups associated with beam therapy. A clinical audit programme was in place, which included work on radiotherapy outcomes, in addition to examples of audit in chemotherapy and elsewhere. We found that risks were managed with appropriate escalation from the oncology centre to the division and into the trust’s system. A
pilot scheme was in place to test a risk management system which includes specific models for cancer and diagnostics. We identified clear learning from the logging and analysis of errors and ‘near-misses’. The centre had also reviewed practice and procedures following the Beatson oncology incident.

Although it had been adversely affected by some staffing difficulties, there was evidence of development work and the centre had been using intensity modulated radiation therapy (IMRT) for several years. It was reported that the planned relocation would provide further opportunities to develop services including the introduction of new techniques such as image guided radiation therapy (IGRT).

**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. The trust also provided the Commission with assurance that it had procedures in place that met regulatory requirements and that risks were being managed within the centre’s governance structures.

Written procedures and protocols were in place, duty holders were identified and adequately trained, appropriate records were kept and clinical audit and risk management were carried out. During the inspection, in areas where working practice was observed, we found that practice mirrored the relevant written procedures and that there was cooperation between duty holders and multi-disciplinary groups. The only point to note from the inspection was that the integration of IR(ME)R procedures and associated working instructions required further development and that the management of the QART system could be improved.

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<th>Regulation</th>
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<td><strong>Regulation 4:</strong> Duties of Employer</td>
<td>The centre should review the various written procedures and associated work instructions relevant to IR(ME)R, with the aim of ensuring improved integration and cross-referencing where appropriate, all included within the QART. We support the recommendation from the accreditation body that the management of the QART system should be improved.</td>
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