Experiences of a proactive IR(ME)R inspection in radiotherapy

A NISBET, PhD, MIPEM and M COCKER, MSc, MIPEM

Department of Medical Physics and Bio-Engineering, Raigmore Hospital, Highland Acute Hospital NHS Trust, Old Perth Road, Inverness IV2 3UJ, UK

Abstract. The Ionizing Radiation (Medical Exposure) Regulations 2000, IR(ME)R, apply to the safety of the patient referred for a medical exposure to ionizing radiation. In Scotland, the Scottish Executive (Department of Health) is responsible for carrying out inspections of compliance with these regulations. IR(ME)R specifically addresses issues concerned with Employer's duties, responsibilities of the Practitioner, Operator and Referrer, justification of individual medical exposures for diagnosis and treatment, optimization of all procedures, clinical audit and adequate training of all duty holders. A proactive IR(ME)R inspection of the Clinical Oncology Department, Raigmore Hospital, Inverness, was carried out in November 2001 by inspectors based at the Department of Health, London, and seconded by the Scottish Executive, Department of Health. The aim of the inspection was to assess the degree of compliance with the regulations. In this case study the experiences of a proactive inspection are described in detail and some of the important elements of implementing IR(ME)R in a department that operates an ISO 9000-2000 Quality Management System addressed. The identification of IR(ME)R Duty Holders' responsibilities is one important aspect which may be inadequately described by the existing Quality Management System documentation. Other key elements of the inspection include the methods of authorizing the justification, the importance of the treatment prescription sheets in the demonstration of compliance with IR(ME)R, patient identification and pregnancy questions and dose recording procedures. The integration of the standard operating procedures as described in Schedule 1 of the regulations is also important. Where the existing Quality Management System documentation is written to include the IR(ME)R requirements of duty holder's responsibilities and the allocation of all the important tasks, then there is no need to re-badge these documents for IR(ME)R purposes. IR(ME)R encourages departments to focus on the safety of the patient and to document good practice. In order to comply, departments will have to show evidence of optimization of their procedures and must address the clinical governance issues associated with delivery of treatment.

In the last few years new legislation governing the use of ionizing radiation in medical and dental practice and in allied research involving human subjects has been published. This includes the Ionizing Radiations Regulations 1999 (IRR99) [1] and its Approved Code of Practice (ACoP) and non-statutory guidance [2], the Ionizing Radiation (Medical Exposure) Regulations 2000 (IR(ME)R) [3] and supporting guidance [4]. Medical and dental guidance notes (MDGN) [5] have also been prepared as a guide to good radiation protection practice on the use of ionizing radiation in medicine and dentistry. The latter includes practical advice related to some, but not all, of the requirements of the above legislation. It is necessary that employers and those that advise them are fully aware of these requirements and those of other relevant acts or regulations such as the Medicines (Administration of Radioactive Substances) Regulations 1978 [6] and subsequent amendment [7] and the Radioactive Substances act 1993 [8].

In Scotland, the Scottish Executive (Department of Health) is responsible for carrying out inspections of compliance with IR(ME)R. IR(ME)R specifically addresses the clinical governance issues concerned with Employer's

duties, responsibilities of the Practitioner, Operator and Referrer, justification of individual medical exposures for diagnosis and treatment, optimization of all procedures, clinical audit and adequate training of all duty holders.

Against this background a proactive IR(ME)R inspection of the Clinical Oncology Department, Raigmore Hospital, Inverness was carried out in November 2001 by inspectors based at the Department of Health, London, and seconded to the Scottish Executive, Department of Health. The aim of the inspection was to assess the degree of compliance with the above regulations.

In this case study the experiences of the proactive inspection are described in detail and some of the important elements of implementing IR(ME)R in a department that operates an ISO 9000-2000 Quality Management System [9] are addressed. The identification of IR(ME)R Duty Holder's responsibilities is one important aspect which may be inadequately described by existing Quality Management System documentation. Other key elements of the inspection include the methods of authorizing the justification, the importance of the treatment prescription sheets in the demonstration of compliance with IR(ME)R, patient identification and pregnancy questions and dose recording procedures. The integration of the standard operating procedures as described in Schedule 1 of the regulations is also important. Although Pearson et al have described a generic approach to risk assessment [10] and the MDGN provide a good practice guide to radiation protection in the clinical environment we are unaware of any publication in

Received 21 May 2003 and in revised form 28 August 2003, accepted 24 September 2003.

Current address for Dr A Nisbet, Department of Medical Physics & Clinical Engineering, Churchill Hospital, Old Road, Headington, Oxford OX3 7LJ, UK.

the literature which addresses the requirements of a radiotherapy IR(ME)R inspection specifically. It is hoped this paper will be of help to departments seeking to implement IR(ME)R requirements successfully.

Materials and methods

Format of inspection

As a proactive inspection the period of notice is of the order of several weeks, and although proactive, Notifications or Enforcement Notices may be issued if any practices are identified as contravening the legislation. The inspection itself covered radiology, nuclear medicine and primary care dental facilities in addition to radiotherapy, although the latter area only is discussed in this paper.

The format involves a pre-inspection meeting between inspectors and senior managerial staff of the Trust, the actual inspection, a post-inspection briefing and subsequent written report. Also implicit within the format is action taken as a result of the inspection, this may occur during the inspection, immediately after the briefing meeting or following receipt of the written report, dependent on the degree of non-compliance with legislation. It is anticipated that any subsequent inspections would involve initial review of earlier inspections.

It is important that senior managerial staff of the Trust attend both pre- and post-inspection briefings. As far as possible the following staff or equivalent should be present: Chief Executive, Medical Director, Clinical Risk Manager, Directorate Manager, Radiation Protection Advisor, Head of Clinical Oncology, Superintendent Radiographer and Head of Radiotherapy Physics. The immediate line managers and ultimately the Chief Executive are directly responsible for implementing the IR(ME)R regulations and should be able to show awareness and support at these briefings. At the post-inspection briefing the inspectors ensured that the management representatives were aware of the importance of acting on recommendations made.

The actual inspection primarily involves a methodical progression through each regulation with written procedural evidence being required to demonstrate compliance with each regulation. The range of documentation necessary to make available for inspection includes Standard Operating Procedures for IR(ME)R 2000 Schedule 1 and Quality Management System Documentation, in particular appropriate work instructions and procedures. This, out of necessity, involves the interviewing of senior departmental staff members to answer questions and provide ease of access to appropriate documentation.

Following the detailed analysis of written departmental documentation, time is taken to assess staff awareness of optimized procedures, and the practical implementation of the above documentation.

Results and discussion

The inspection identified some issues where compliance with the legislation could be improved, namely Responsibilities and Duty Holders and also some aspects of Justification and Optimization. It was found that other important issues such as Training and Clinical Audit are more easily interpreted to ensure compliance. Examples

arising from the inspection are provided for each of these issues.

Responsibilities and Duty Holders

It is essential to provide written procedures, which identify those tasks that may affect patient safety or have an influence on the optimization of treatment. These procedures should explicitly identify those staff with duty holder roles. This is best and most easily done through modification of existing Quality System Documentation where a "Responsibility" section may explicitly name those staff acting as Referrer, Practitioner or Operator. In particular the scope of Referrals for clinical oncologists, *i.e.* Referrers for simulation, CT planning and treatment, should be explicit within procedures. In departments where radiographers, physicists or clinical technologists may also act as Referrers and Practitioners for concomitant exposures such as portal images or re-simulation verification then the procedures and responsibilities should be described in detail. Where one person has multiple duty holder roles then procedures should indicate for example that the referral, justification and authorization for radiotherapy is always carried out by one person, who signs in a designated place.

It is also essential that all important tasks have been identified and that responsibility for those tasks has specifically been allocated. Thus it is insufficient to identify a group of staff as being responsible, *e.g.* simulator radiographers. It must be absolutely clear who does what, *i.e.* a specific individual. This is best illustrated by considering the Treatment Prescription Sheet. The procedure describing the completion of the Treatment Prescription Sheet should be unambiguously clear as to what information is required to be filled in, what actions should be taken if not all information is written in, and what each signature on the treatment sheet is actually confirming. For example radiographer operator "A" will actively identify the patient, identify the patient's immobilization and/or other accessories, accurately set up the patient on the couch using check list and sign the treatment prescription sheet in the allocated box to indicate that they specifically have carried out the tasks. Radiographer operator "B" should check that confirmatory signatures have been provided by radiographer operator "A" to indicate that all patient set up tasks and checks have been carried out satisfactorily and then initiate exposure. A signature on the treatment prescription sheet in the allocated box indicates that they specifically have taken responsibility for this. It is thus essential that a specific work instruction/procedure describing the operation of all radiotherapy equipment be produced to describe all important Operator duties.

Justification

As an example Regulation 6(1)e states that "no person shall carry out a medical exposure unless, in the case of a female of childbearing age, he has inquired whether she is pregnant or breastfeeding". The inspectors thus require documented procedures explicitly stating the responsibility and method for confirming pregnancy status. In addition to providing the patient with information on risks to an unborn child, they must be advised to avoid pregnancy

during treatment. A pregnancy declaration should be completed by the Practitioner and patient to indicate to the Operator who initiates the exposure that pregnancy has been considered and excluded and that treatment can proceed.

Some modifications to departmental procedure were required to ensure that responsibilities were clearly defined. For example the clinical oncologist, acting as Practitioner, is responsible for establishing whether a female patient of childbearing age is pregnant before any exposure to radiation. A pregnancy test or blood sample is carried out where required. The clinical oncologist also discusses with the patient the risks of radiation to an unborn child and both the clinical oncologist and patient sign a pregnancy declaration on the treatment prescription sheet, without which treatment may not be initiated by the Operator. An example of a pregnancy declaration proforma is shown in Appendix A.

A procedure should also be in place describing the methods to be used to assess the dose to the fetus and the dose reduction methods required in the event of a patient having to continue treatment whilst pregnant.

Optimization

Patient identification is one particular issue an inspection may be expected to focus upon. The inspector thoroughly examined the documented procedures in place. To ensure consistency and adequate implementation, staff were asked what their responsibilities were to make sure patient identification and procedures and methods for confirming that the patient had been identified correctly were observed. Modifications to the Trust's general procedure and specific radiotherapy procedures following inspection now state that the radiographer who prepares and sets up the patient for a radiation exposure is responsible for the formal identification of that patient and for supplying the confirmatory signature. The patient is actively asked to state their name, date of birth and address and the procedures also consider patients who are deaf, anaesthetised or unconscious, foreign or have language difficulties.

Evidence of Standard Clinical Protocols is also required, and departments where these do not exist would be considered out of step with the rest of the United Kingdom. Such protocols should include details of the dose, fractionation scheme, specific treatment technique, treatment aids that might be used and should specify any circumstances which might arise where an Operator must refer to the Practitioner, or consult a Medical Physics Expert, before proceeding with treatment. The treatment of benign conditions should also be considered and special procedures for non-standard treatments should be in place thereby providing a higher level of security.

With regard to dose summary requirements the inspector wished to see a patient dose summary record produced at the end of treatment which included an assessment of dose from portal verification imaging and simulator and CT sessions. The individual responsible for producing the end of treatment summary should also confirm the accuracy of the treatment sheet. Obviously any mistake discovered after treatment is complete is not ideal and periodic checks of the accuracy of the treatment sheets should be carried out during treatment. Again documented evidence of the department's policy for this should be available.

It is important to demonstrate universal staff agreement with the optimized procedures and for staff to be able to demonstrate that signatures are being provided for the particular responsibilities and duties.

Training and clinical audit

It is essential that written training records are available to demonstrate that staff undertaking particular responsibilities have been suitably trained. There should be evidence that Operators have been trained on the use of the individual units of equipment. In addition written procedures for ensuring that all staff and records are kept up to date with training requirements should be considered. Clinical audit should be carried out as required.

Conclusion

An IR(ME)R inspection may be considered the only means of assessing that a department is actually complying with legislation, as it provides an inspectors interpretation of the procedures' compliance with relevant legislation. The inspectors can sometimes offer more effective methods of implementing the requirements of the legislation.

It is important for individual radiotherapy centres to review and analyse existing Quality System documentation to ensure that responsibilities and duties are explicit. It is also essential for confirmatory signatures to identify unambiguously who has taken responsibility for which actions. In particular it is important to consider if all tasks that may have an influence on patient safety, or the optimization of treatment, have been adequately described in the documented procedures.

The provision of a comprehensive Duty Holders list is also best accomplished by modifying the existing Quality System documentation to ensure that Referrers, Practitioners and Operators in each process are identified.

References

1. IRR99. The Ionising Radiations Regulations 1999 (SI 1999 No 3232) London: HMSO, 1999.
2. L121 HSE. Work with ionising radiation. Approved Code of Practice and practical guidance on the Ionising Radiations Regulations 1999. London: HSE, 2000.
3. IR(ME)R. The Ionising Radiation (Medical Exposure) Regulations 2000 (SI 2000 No 1059). London: HMSO, 2000.
4. DoH. The Ionising Radiation (Medical Exposure) Regulations 2000 (together with notes on good practice). London: DoH (2001) www.doh.gov.uk/irmer.htm
5. IPeM. Medical and Dental Guidance Notes. A good practice guide on all aspects of ionising radiation protection in the clinical environment. York: IPeM, 2002.
6. MARS78 Medicines (Administration of Radioactive Substances) Regulations 1978 (SI 1978 No 1006). London: HMSO, 1978.
7. MARS95 Medicines (Administration of Radioactive Substances) Regulations 1995 (SI 1995 No 2147). London: HMSO, 1995.
8. RSA93 Radioactive Substances Act 1993 (chapter 12). London: HMSO, 1993.
9. British Standards Institute, BS EN ISO 9001-2000: Quality Management Systems – Requirements.
10. Pearson D, Rogers AT, Moss E. A generic approach to risk assessment for the ionising Radiations Regulations 1999. Br J Radiol 2001;74:62–8.

Appendix A: Sample pregnancy declaration proforma

Pregnancy Declaration

Pregnancy Discussed: Yes/Not Applicable Pregnancy has been excluded Signed (Clinical Oncologist)

Date/...../.....

I confirm that I am not pregnant. I understand that radiation and anti-cancer drugs can harm an unborn body, and that I should adequately protect against pregnancy during the course of anti-cancer treatment. Also, if I miss a period or there may be the possibility of pregnancy, I will immediately inform the medical staff.

Signed (Patient)

Date/...../.....

PROOFS

The British Journal of Radiology
36 Portland Place
London
W1B 1AT
Tel +44 (0)207 307 1400
Fax +44 (0)207 307 1414
Email publications@bir.org.uk

Dear Author,

Please find enclosed a proof of your article “**Experiences of a proactive IR(ME)R inspection in radiotherapy**” for checking.

When reading through your proof, please check carefully author’s names, scientific data, data in tables, any mathematics and the accuracy of references. Please do not make any unnecessary changes at this stage. All necessary corrections should be marked on the proof at the place where the correction is to be made; please write the correction clearly in the margin (if in the text they may be overlooked).

Please also check the quality of any bromides supplied for halftone images – these represent the quality of the image when printed.

Any queries that have arisen during preparation of your paper for publication are listed below and indicated on the proof. Please provide your answers when returning your proof.

Please return your proof by Fax (+44 (0)207 307 1414) within 2 days of receipt.

BJR OFFPRINT ORDER FORM

The British Journal of Radiology, 36 Portland Place, London W1B 1AT

NB Please return this form even if you do not wish to order any additional offprints.

MANUSCRIPT DETAILS

Reference no. _____ No. of pages _____ Expected month of publication _____

25 free offprints will be supplied to the corresponding author of each article appearing in the BJR (other than Letters to the Editor). Additional offprints (in batches of 25) may be ordered at the rates given below.

RATES (includes UK second class/overseas surface mail postage)

No. of pages	Rates per 25 <u>additional</u> offprints (as printed)
1-2	£9.75
3-4	£15.60
5-6	£21.30
7-8	£27.20
9-10	£29.40
11-12	£32.20
13-16	£50.70

For **all** offprints to be bound in covers (including 25 free copies) add £12.70 per 25 copies

- For overseas authors, the option of offprint delivery by **airmail** is available ●

For information, a **rough** guide to airmail postal rates is given in the following table (based on a 6 page article).

Please note: authors will be charged **at cost** for airmail delivery.

No. offprints	Postal rates		
	Airmail (Europe)	Airmail Zone 1 (Americas/Middle East)	Airmail Zone 2 (Far East/Australasia)
25	£1.70	£3.70	£4.40
50	£3.00	£7.00	£8.40
100	£5.60	£13.50	£16.00

- Please complete the following details (print in capitals):

Please supply offprints in addition to my 25 free offprints (supplied for all articles other than Correspondence)

Offprints bound in covers: tick box if covers are required ☐

Overseas authors: tick box if delivery by overseas airmail is required ☐

Name and address to which offprints are to be sent: _____

Please return this form with your checked proof. Please do not send payment now. You will be invoiced following publication of your article. Please give invoicing address if different from above: