X-RAYS, THE LAW AND YOU. WHY YOU MUST UNDERSTAND THE NEW REGULATIONS

C Spry, Head of Department of Radiology,
Westmorland General Hospital

INTRODUCTION

An important law in medical practice has changed, and you need to know about it. In May 2000, the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R 2000) were introduced, to replace the Ionising Radiation (Protection of Persons Undergoing Medical Exposure and Treatment) (POPUMET) Regulations 1988. This piece of legislation will have an impact on the way in which patients can be referred for examination, and how radiology departments deal with the requests. What is, at present, merely good practice becomes a legal requirement. It is another strand of clinical governance.

The regulations include advice about maintaining exposures to levels 'as low as reasonably practicable', advice about equipment quality, maintenance and quality assurance. They also stress the need for justification of a medical exposure which requires practitioners to do two things, namely, a risk/benefit assessment for every patient (or population) and consideration of alternative techniques which use less radiation or none at all. Thus, the potential value for each exposure will need to be assessed in advance to ensure that the benefits to the patient or to society outweigh the risks of the exposure.

The IR(ME)R 2000 regulations have also changed the areas of responsibility and now place a greater emphasis on the responsibility of the person who delivers the medical exposure (the operator). In Morecambe Bay, this person will usually be a consultant radiologist, a specialist registrar or a radiographer.

HOW DO X-RAYS HARM LIVING TISSUE?

X-rays cause ionisation of molecules within cells. This action generates free radicals which are mobile and highly reactive. They damage DNA which may cause cell death or failure to replicate. Doses given in diagnostic radiology for **single examinations** are usually well below the postulated threshold for acute effects such as depression of haematopoiesis, ovarian sterility or detectable opacities in the lens of the eye. Radiotherapy uses these very effects of ionisation to kill cancer cells but it also kills normal cells in adjacent tissue in the therapy beam. Therapeutic doses are many thousands of times higher than diagnostic doses.

Low dose radiation can induce cancer or hereditary effects as a result of a damaged cell surviving in a modified form and cloning itself. After a latent period, often many years, this may induce a cancer in an individual or, if present in gonadal cells, may be passed on to offspring causing hereditary defects. However low they are, radiation doses are not entirely without risk. For this reason, statutory regulations

(IR(ME)R 2000) require everyone concerned to reduce unnecessary exposure to radiation and to ensure that clinical benefits to the patient outweigh the (very) small radiation risks.

DIAGNOSTIC MEDICAL EXPOSURES

- diagnostic medical exposures add about 16.6% to population dose from background radiation each year in the UK. They are the main source of manmade radiation.
- the NHS has more workers with occupational exposure than the nuclear industry. The latter is more heavily regulated by far.
- dose may be imagined using Table 1. If a **chest X-ray** has a dose of one unit, it is equivalent to the dose from **normal background radiation from three days in Cornwall**.

X-RAY EXAMINATION	EQUIVALENT NUMBER OF CHEST X-RAYS	EQUIVALENT PERIOD OF NATURAL BACKGROUND RADIATION
limb	1/2	1 day
chest	1	3 days
spine (dorsal)	35	4 months
spine (lumbar)	65	7 months
pelvis	35	4 months
IVU	125	14 months
Ba enema	350	3.2 years
CT chest	400	3.6 years
CT abdomen or pelvis	500	4.5 years
lung V/Q scan	65	8 months
bone scan	200	1.8 years

Table 1 Medical radiation dose

- tomography (CT) scans now contribute about half the collective national dose.

THE KEY REGULATIONS (IR(ME)R 2000) RELEVANT TO YOU

You need to understand:

- new definitions of personnel
- how to identify personnel
- duties of personnel
- the process of justification
- authorisation of requests
- evaluation of medical exposure
- how practice will change

NEW DEFINITIONS OF PERSONNEL

EMPLOYER – any natural or legal person who, in the course of trade, business or other undertaking, carries out

(other than as an employee), or engages others to carry out medical exposures at a given radiological institution (eg the acute trust, the Nuffield organisation, a dental surgery).

REFERRER – a registered medical or dental practitioner or other health professional who is entitled in accordance with the employer's procedures to **refer** individuals to a practitioner for medical exposure. The referrer must provide a request card complete with enough clinical information for the examination to be justified (eg any doctor).

PRACTITIONER – a registered medical or dental practitioner who is entitled in accordance with the employer's procedures to **take responsibility** for an individual exposure (eg a radiologist).

OPERATOR – any person who is entitled, in accordance with the employer's procedures, to **carry out** any practical aspect associated with the exposure (eg a radiographer).

It is possible that a person can fall into more than one of these categories, ie a consultant radiologist will be the practitioner and the operator during fluoroscopic procedures.

Morecambe Bay Hospitals NHS Trust is responsible for identifying the people who fall into the above categories, and a procedure is being developed in order to do this. Note the emphasis on 'employers' procedures'. This will force a re-evaluation of current practices and the development of new guidelines, protocols and procedures within hospitals and between primary and secondary care.

HOW TO IDENTIFY PERSONNEL

REFERRERS

Category	Expected level of training	Scope of referral
hospital consultant	Royal College accreditation specialist register	all examination types and interventional procedures
non-consultant hospital doctors	medical degree	all diagnostic examinations as laid down in directorate protocols
nurse practitioners	nursing degree plus in-house training	only those procedures laid down in the directorate protocols
general practitioners	medical degree	all plain film radiography as laid down in the directorate protocols
general dental practitioners, oral surgeons and orthodontists	dental/medical degree	appropriate plain radiography of the head and jaw

PRACTITIONERS

Category	Training requirements	Scope of justification
consultant radiologists and radiology SpRs	FRCR	all examination types and interventional procedures
radiographers	radiography degree/diploma plus in-house training	all plain film examinations as laid down by departmental protocols
cardiologists	MRCP + cardiology diploma	all cardiology procedures

OPERATORS

Practical aspects	Category	Training requirements
performing all plain film radiography	radiographers	radiography degree/diploma
taking the lead performing barium enemas	consultant radiologists, SpRs, radiographers	FRCR or radiography degree plus barium enema training course
taking the lead performing interventional and fluoroscopic procedures (except barium enemas)	consultant radiologist or SpR	FRCR
assisting during interventional and fluoroscopic procedures (except barium enema)	consultant radiologists, SpRs, radiographers	FRCR or radiography degree/diploma + in-house training
performing fluoroscopy during orthopaedic procedures in theatre	consultant radiologists, SpRs, radiographers	FRCR or radiography degree/diploma + in-house training.
performing CT scans	consultant radiologists, SpRs, radiographers	FRCR or radiography degree/diploma + in-house CT training
all cardiology procedures	cardiologists or consultant radiologists	FRCP + cardiology diploma
in-house QC on X-ray equipment	radiographers/helper	radiography degree/diploma and/or in-house training
QC (including testing before use and routine level B tests)	approved medical physics dept RLI/Breast Unit – North West Medical Physics FGH/WGH – Northern Region Medical Physics	training provided by North West Medical Physics Dept or Northern Region Medical Physics Dept
film processing and QC	radiographers, radiographer helpers and healthcare assistants	in-house training

DUTIES OF PERSONNEL

- all must comply with the employer's procedures
- the **practitioner** is to **justify** all medical exposures
- the **operator** is responsible for all practical aspects of his/her exposure
- the **referrer** shall supply sufficient medical data to enable the **practitioner** to justify the medical exposure and the **operator to authorise it**
- the practitioner and operator shall cooperate with other specialists involved in a medical exposure
- all medical exposure must be **authorised** by the **practitioner** or **operator**, ie certified that the referral is within the protocols laid down
- where it is not practical for the practitioner to authorise the exposure, the operator shall do so in accordance with guidelines written by the practitioner.

THE PROCESS OF JUSTIFICATION

The IR(ME)R regulations state that all medical exposures must be justified. This is the responsibility of the practitioner (in our case, the radiology department), who will write guidelines and protocols that must be followed.

Our protocols are based on 'Making the best use of a department of clinical radiology', from the Royal College of Radiologists. Copies are available on the intranet and also in the education centre of all main hospital sites.

Any referrals involving ionising radiation must fall within the protocols. If not, the request must be discussed with the consultant radiologist, who, acting as practitioner, can justify the request if appropriate.

The following factors inform the process of justification:

- the appropriateness of the request, eg will this 'routine' pre-operative chest X-ray contribute to management?
- optimisation of the imaging strategy, eg can we use ultrasound instead of an IVU or CT scan?
- the risk versus benefit, eg is a lumbar spine radiograph appropriate in acute onset sciatica?
- understanding the immediate and cumulative effects of ionising radiation
- consideration of age, eg is there an alternative (no dose or lower dose) examination in children
- urgency of the exposure, eg if the patient is pregnant, can the examination wait until after delivery?
- the efficacy of imaging in different clinical situations
- appropriate delegation, eg a nurse practitioner referring patients for x-ray under directorate protocols
- evaluation of exposures that have no health benefit to the individual, but have a perceived benefit to society, eg 'employment' chest X-rays

AUTHORISATION OF REQUESTS

All requests must be authorised prior to exposure. In Morecambe Bay this will normally be done by the radiologist or radiographer who undertakes the examination. Authorisation indicates that the request lies within the protocols. The radiographer will sign the request card to indicate that this process has taken place.

EVALUATION OF MEDICAL EXPOSURES

IR(ME)R states that every medical exposure should be clinically evaluated and reported. Evaluation refers partly to record-keeping about exposure factors and partly to a record that the resultant image has actually been examined.

The majority of films taken in Morecambe Bay will be reported by a consultant radiologist.

Films that do not need a radiologist's report, eg orthopaedic check films, must be evaluated by the referrer, using protocols agreed with them. A record of the evaluation should be kept.

Dental films taken and sent with the patient must be evaluated by the referring dentist, and a record kept with the dental notes.

Medical exposures during fluoroscopy for guidance, eg ERCP or theatre work, will be recorded by the radiology directorate, but the evaluation must be recorded by the doctor performing the procedure. For example, an entry should be made in the case notes stating that an ERCP showed contrast in the biliary tree (or not, as the case may be).

HOW PRACTICE WILL CHANGE

The **biggest single** consequence is that most current practice will have to be reviewed. Every user of our service will have to become more careful about radiation. This will require good cooperation between you and us. We need you to help develop our protocols and ensure that they are observed. This could be time-consuming.

Radiographers will challenge requests

The radiographer must first authorise the exposure. This process will determine whether the request falls within the departmental protocols. If so, the examination will go ahead. The radiographer will record that authorisation has been given, and will also note all relevant dose details. If not, the radiographer is **legally** bound to question the request, and **must** refuse the referral if he/she is not happy to authorise the request with the information given. The referrer should contact the radiologist, who may justify the medical exposure appropriate.

Other consequences

- request cards will be returned if
 - cast iron identification of the patient is not possible from the request
 - there is insufficient or inappropriate clinical data
 - any other factors prevent justification or authorisation
- films will **not be repeated** for convenience if
 - temporarily missing (in transit, not in clinic)
 - at a known location but unavailable at the time of a clinic
- it will not be acceptable to do some tests twice for the same problem. For example, radiographs done prior to a referral to a hospital clinic are repeated unthinkingly when no change in symptoms has occurred
- fluoroscopy by trainee doctors will not be permitted unless they have received approved training
- films which are not reported by radiologists must be evaluated by those who use them. There is a duty on you to develop systems to make this happen if you receive films which will not be reported by radiologists
- some access to service will be withdrawn or severely restricted. Lumbar radiographs are high dose, common studies which are frequently not justifiable
- radiographs on immigrants, intending emigrants and on prospective employees may be stopped unless justified by symptoms, signs or other clinical factors
- high dose studies, such as CT scans, may be done differently. You may receive different images to what you expect. You may be asked to accept a **different test** instead (eg ultrasound). Repeat scan intervals will be scrutinised.

SUMMARY

The IR(ME)R regulations have been introduced in order to provide a dose "as low as reasonably achievable" for all persons undergoing exposure to ionising radiation for medical purposes. They aim to limit the number of medical exposures to those which are necessary. The regulations must

be fully in place on 1st January 2001, and the radiology directorate is working closely with the appointed radiation protection advisers to meet this deadline.

We have always worked on the basis that every exposure should be justified. IR(ME)R makes this a legal requirement and formalises the process. Practitioners have a duty to justify all exposures which will be done in the form of protocols.

Radiographers in Morecambe Bay have always been encouraged to question "inappropriate requests", but will now have a duty to do so by law.

All requests for medical exposure must be authorised, and, in Morecambe Bay, this task will be delegated to the operator.

We hope to get cooperation from all referrers, especially while we familiarise ourselves with the changes. If you get a call from a radiographer asking questions about your requests, please be gentle with them. They are only doing their duty according to IR(ME)R.

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