Editorial

THE IONISING RADIATION (MEDICAL EXPOSURE) REGULATIONS (IRME) 2000 – RADIOLOGICAL CONSIDERATIONS

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The IRME regulations cover all aspects of the medical exposure of individuals to ionising radiation, but only a very few items are relevant to clinicians. The regulations do not apply to doctors and other health-care professionals directly, but make the hospital trust accountable for the safety of radiological exposure. Each trust is required to produce a series of local regulations defining the safe use of medical radiation in its premises and must have written procedures covering all aspects of radiological exposure. IRME regulations apply to both the National Health Service and the private sectors. Responsibility for ensuring compliance with the regulations has been passed to the Health and Safety Directorate.

The items which are of interest to clinicians are those relating to the reporting of radiographic examinations.

General application

It is now unlawful for a radiographic examination to be requested, or performed, if it is known that it will not be reported on. Almost certainly, a corollary of this is that it is unlawful to request or to perform a radiological examination for which there is no clinical need or anticipated benefit to the patient except for medicolegal purposes. Radiographers are now charged with ensuring that a clinical indication is recorded before an examination is carried out, and have the authority to refuse to do a requested examination which has no such reference; they can do so without consultation.

All radiographic examinations must be reported by a radiologist or the clinician who requested the examination and the report must be recorded in the patient’s case notes. It is noteworthy that there is no mention of the quality of a report, the information which must be provided in it, or the time by which it must be filed.

These regulations have the force of legislation, and breaches of them could give rise to liability in the criminal as well as the civil courts.

Local trust regulations

A hospital trust will already have local regulations in place, and although the formal IRME directions do not directly regulate hospital clinicians, the local controls will do so and each clinician needs to be aware of them since they will differ from one trust to another. There is no requirement that local regulations state that all examinations must be reported by a radiologist, only that they must be reported in the clinical notes of the patient. Clinicians whose radiographs are not routinely reported by a radiologist will be made responsible for reporting on them and recording them in the case notes. If neither the clinician nor the radiologist is willing to report an examination, the situation must be resolved and written regulations must be produced. Until this is done, it is unlawful for the examination to be performed.

Delegation of reporting and criminal liability

It is now generally accepted, to the point of being a legal requirement, that the delegation of medical duty to another requires that the delegator be satisfied of the competence of the delegatee. This principle is well established in all medical situations, and it is assumed that delegation by radiologists to registrars in training or to radiographers, as well as by clinicians to registrars in training or nurse practitioners, is not allowed until the competence of these individuals has been tested. There is no regulation prohibiting the delegation of reporting.

There is no suggestion in the regulations that a radiologist is delegating reporting to his clinical colleagues, or that the competence of a clinician to report examinations which he requests needs to be established, tested or verified. Thus there is no regulation which covers the problem of examinations which contain important diagnostic material which is not in the field of expertise of the clinician who is interpreting the examination. It is our opinion that there is no criminal liability in the production of an incorrect radiological report, whether it be done by a radiologist or clinician, regardless of the examination requested, or the

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field of expertise of either, unless it could be considered negligence, which is already a criminal offence.

Civil liability

The absence of criminal liability does not protect the individual practitioner from civil action, and therefore the interpretation of radiological examinations after IRME will be tested, in the same way as it was before, by the application of the Bolam test. Is the practice deemed to be reasonable by a responsible group of practitioners who have been trained in the same speciality as the accused? Is it that of a reasonable, responsible individual which can be robustly defended (the Bolitho test)? Although the Bolam test depends heavily on the opinion of an expert witness, it must be remembered that the Bolitho criteria of the reasonable and responsible are decided by the court and not by the opinion of an expert witness.

The Bolam test is fragile; it cannot stand up to written evidence or recorded experience, and therefore one must view with considerable alarm a recent paper which showed that the interpretation of radiographs by using the light from a window is not as good as if a view box is used. We doubt that it would be possible, now, to defend the inspection of radiographs on a ward-round by holding them up to the window, even although this practice would have been acceptable by the Bolam test until recently.

There is already at least one judgement against a radiologist, accused of radiological negligence, for failing to report an examination which he had not seen and did not know existed. After IRME, this could easily happen to a clinician.

We wait with interest for the first case claiming negligence for missing a lesion in an area not in the area of expertise of the clinician. The case report on page 896 of this issue of the Journal illustrates how radiographs should be reported with careful attention being paid to body systems other than the symptomatic one, but the reader will appreciate that subtleties can and will be missed. Currently, this is not the rarest reason for the action for medical negligence against a radiologist, and it is only a matter of time before a clinician, rather than a radiologist, will be involved. Here, the Bolam test will be applied.

Summary

1) IRME regulations apply to the trust and not to the individual clinician.
2) Each trust must have written regulations outlining how the IRME regulations are to be applied locally.
3) The IRME regulations and, almost certainly, the local directions, have the force of the law and breaches may be dealt with by both the criminal and the civil courts.
4) All radiological examinations using ionising radiation must be reported either by a radiologist or a clinician, and the report must be filed in the patient’s case notes.
5) It is unlawful to request a radiological examination if it is not to be reported.
6) No regulation mentions the quality or timeliness of the radiological report.