REGULATION OF WORK WITH IONISING RADIATIONS IN THE MEDICAL SECTOR IN GREAT BRITAIN

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1. INTRODUCTION

Within Great Britain the risks to employees and members of the public arising from work with ionising radiations is regulated by the Ionising Radiations Regulations 1999 (IRR99) and the Radioactive Substances Act 1993 (RSA93), which together implement most of the requirements of the Basic Safety Standards (BSS) Directive 96/29/Euratom. Radiation protection of those undergoing medical exposures is regulated by the Ionising Radiation (Medical Exposure) Regulations 2000 (IRMER2000) and by regulation 32 of IRR99, which implement the requirements of the Medical Exposures Directive 97/43/Euratom.

IRR99, which are made under the Health and Safety at Work etc Act 1974 (HSWA74), are enforced by the Health and Safety Executive (HSE). Enforcement of RSA93 falls to the Environment Agency (EA), in England and Wales and the Scottish Environment Protection Agency (SEPA). The Health Departments for England, Scotland and Wales enforce IRMER2000.

Ionising radiation is used in many aspects of healthcare for diagnosis, therapy and medical research in areas such as radiology, radiotherapy, nuclear medicine and pathology. A wide range of types of ionising radiation is used including x-rays, photon and electron beams, and beta and gamma radiation from sealed and unsealed radioactive materials.

IRR99 have been in force since 1st January 2000 and replaced the Ionising Radiations Regulations 1985. The effect on the medical sector of implementing IRR99 should have been minimal, if employers were complying fully with the requirements of the earlier legislation. To support IRR99, HSE has published an approved code of practice and non-statutory guidance (L121)[1] and a series of information sheets aimed at employers. In addition, HSE produces a bi-annual newsletter "Radiation Protection News" which is downloadable from the HSE web site at http://www.hse.gov.uk/hthdir/noframes/iradiat.htm. The web site contains further general information on ionising radiation and radiation protection. The HSE has also been active in the development of sector specific guidance by the various professional bodies involved in health care.

In addition to IRR99, other regulations made under HSWA74 will also apply to work with ionising radiation. The most important of these are the Management of Health and Safety at Work Regulations 1999 (MHSWR99) which require, amongst other things, risk assessments to be made for all work, the implementing of control measures to ensure the health and safety of employees and others, and the monitoring and review of assessments and control measures at appropriate intervals.

This paper is concerned principally with the impact that IRR99 has had on the medical sector. The legislation enforced by other statutory bodies is not considered. Inspections and investigations undertaken by HSE have demonstrated that compliance with IRR99 has been poor in the medical sector. The main areas of non-compliance are in the areas of risk assessments, maintenance and testing of engineering controls, monitoring of designated areas, training of employees, provision of information to employees and others, and quality assurance (QA) of equipment used for medical exposures. These issues will be explored in subsequent sections.

2. RISK ASSESSMENT

IRR99 require an employer to carry out a prior risk assessment before carrying out a new activity involving work with ionising radiation. The purpose of the risk assessment is to identify what measures the employer must take to restrict the exposure of employees and others to ionising radiation. This complements the related requirements for risk assessment in MHSWR99. When the new work commences, the requirements in MHSWR99 for recording the assessment, and keeping it up to date when there have been significant changes in the matters to which it relates, will apply. MHSWR also require the employer to make arrangements for effective planning, organisation, control, monitoring and review of any preventative and protective measures that are put in place as a result of the assessment.

The need for a prior risk assessment under IRR99 only applies to new work activities commencing after 1st January 2000. Work that was already underway when IRR99 came into force should have had an existing risk assessment under MHSWR99. Such risk assessments should have been reviewed post January 2000 to ensure that they were still suitable and sufficient in the light of the requirements in IRR99.

There is a specific requirement in IRR99 for assessment of possible radiation accidents and the putting into place of steps to prevent and limit the consequences of such accidents. Contingency plans are required for any reasonably foreseeable radiation accident.

Inspections and investigations undertaken by HSE inspectors since January 2000 have shown that employers have not carried out suitable and sufficient risk assessments for their work with ionising radiation, either under MHSWR99 or IRR99, and in many cases assessments for possible radiation accidents have not been done. Many employers who were working with ionising radiation prior to the coming into force of IRR99 appear not to have reviewed their existing risk assessments or considered the guidance in L121; indeed many employers still do not have risks assessments for much of their work with ionising radiation. In the majority of cases contingency plans are either non-existent or not suitable or sufficient. Enforcement action, in the form of the issuing of improvement notices has been taken where risk assessments have been found to be not suitable or sufficient. Improvement notices are legal documents that require the actions identified in them to be taken within a specified timescale. Failure to comply with an improvement notice is an offence under the HSWA74.

3. MAINTENANCE AND EXAMINATION OF ENGINEERING CONTROLS

IRR99 require the restriction of exposure to ionising radiation of employees and others to be as low as is reasonably practicable [ALARP] and establish a hierarchy of control measures for this purpose. So far as is reasonably practicable, the restriction of exposure should be by means of engineering controls and design features and the use of safety features and warning devices. All the above must be properly maintained and, where appropriate, thoroughly examined and tested at suitable intervals. The employer is required to consult their radiation protection adviser (the radiation protection adviser is the main qualified expert in UK radiation protection legislation) for advice on such examinations and tests. The employer should keep adequate records of maintenance, examinations and tests.

In the medical sector, items that would be covered by the above requirements include interlocks on entrances to radiotherapy rooms, warning signals at entrances to x-ray and radiotherapy rooms, contained work stations in radiopharmacies, installed dose rate alarms etc. In many cases there are two tiers of maintenance, examination and tests - those done in-house and those done by external agencies such as manufacturers' service engineers.

Inspections have shown that employers are not complying with this requirement of IRR99 in the medical sector. In many instances regular maintenance is carried out but there is a failure to record it. Examination and testing of the engineering controls, safety features and warning devices appears to be ad-hoc rather than regular or planned, with few written protocols or procedures and very little in the way of proper records. There have also been problems with external agencies providing sufficient information in visit reports to enable the employer to compile adequate records. The usual method of enforcement has been for HSE inspectors to give verbal and

written advice where minor failings are encountered. Improvement notices have been served where there are substantial failings.

4. MONITORING OF DESIGNATED AREAS

Many areas, including X-ray rooms, radiotherapy treatment rooms and radiopharmacies have been designated as controlled areas by employers because of the potential radiation levels and the need for special procedures to limit exposures. In addition, areas in nuclear medicine departments such as radiopharmacies, patient injection and treatment rooms and laboratories have been designated as controlled areas because of the levels of contamination that may be present. In both cases IRR99 require adequate monitoring of controlled areas to demonstrate that levels of radiation and contamination are satisfactory for continuing work in the areas. Monitoring should be done both inside and outside the boundaries of controlled areas in order to demonstrate the continuing correct designation of the areas.

Much of the monitoring required has not been done in the medical sector or, if it has been done, adequate records have not been kept. In radiotherapy and radiology departments, environmental monitoring has usually been done following the installation of new rooms or equipment. However, periodic monitoring after this, either to demonstrate that working conditions have not changed or following significant changes in working practices, has not been done. In nuclear medicine there have been significant failings in the regular monitoring of areas controlled on the basis of contamination. People leaving such areas are not routinely monitoring themselves or their clothing to ensure that contamination is not spread outside of the designated areas. There is also a failure to monitor inside the controlled areas whilst the work is progressing, to ensure that levels of contamination are acceptable for continuing work. This has led to people receiving doses that are not ALARP and also to the reporting of possible overexposures where dose meters have been contaminated. Enforcement has usually been in the form of improvement notices but employers have been prosecuted where gross failings have occurred.

5. PROVISION OF INFORMATION, INSTRUCTION AND TRAINING

IRR99 reqwuire that employers provide training in radiation protection to all employees who work with ionising radiation. Training should include the risks to health from exposures to ionising radiations, the precautions that should be taken and the importance of complying with the requirements of IRR99. Other employees and persons not closely involved in the work will need suitable information or instruction to avoid being unnecessarily exposed to ionising radiation.

People who need information, instruction and training in the medical sector include radiographers, clinicians, physicists, pharmacists, nurses, managers, porters, and ancillary staff. Those who are given specific roles under IRR99, such as acting as radiation protection supervisors or carrying out the monitoring of radiation and contamination levels in designated areas, will need training specific to their tasks.

Some of the above groups of people have received some radiation protection training in the course of obtaining their professional qualifications. However the employer is responsible for ensuring that any training specific to the work they will be doing is provided. The employer should also ensure that people, such as ancillary staff, who have very little knowledge of ionising radiation are given sufficient instructions and training for them to carry out their duties safely. All training should be documented.

HSE inspectors have found that employers in the medical sector do not adequately address training of employees. Too much reliance is placed on the training received as part of professional qualifications. The training of people such as nurses, porters and other support staff is generally poor. Training records are generally inadequate and non-existent in some cases. HSE investigations into incidents involving ionising radiation have shown that inadequate training and instruction has been a major contributing factor to the incident. Enforcement in the form of improvement notices and prosecutions has been taken in relation to training and information.

6. PROTECTION OF PATIENTS

Regulation 32 of IRR99 places specific duties on employers in control of equipment used for medical exposures. The duties are intended to protect patients from unnecessary exposures to ionising radiation arising out of inadequate or failing equipment and relate to selection of equipment, provision of an appropriate QA programme, and prevention and investigation of exposures much greater than intended which occur as a result of equipment defect or malfunction. Such incidents must also be notified to HSE. The intent of the requirements is to ensure that such equipment is designed, constructed, installed and maintained in a manner which will restrict so far as reasonably practicable the exposure received by persons undergoing medical exposures, consistent with the intended clinical purpose.

The standard of compliance with the QA requirements has been found to vary significantly across the medical sector, ranging from very good, well documented systems in radiotherapy to practically non-existent provisions in some dental radiology practices and alternative medicine modalities (such as chiropractice. In many instances, a lack of staff resources in hospitals has led to the QA programme not being fully implemented in radiology departments. Where some aspects of the QA are carried out by the equipment manufacturer's service engineers, there have been problems with sufficient information being provided when the equipment is handed back to enable the employer to determine if the equipment is safe to return to clinical use.

The employer must decide whether equipment defects or failures have resulted in a patient exposure that was much greater than intended. This requires a professional judgement to be made and the employer would be expected to consult the radiation protection adviser and other appropriate persons, such as the clinician responsible for the patient. To assist the employer, HSE has produced guidelines[2] that it believes are reasonable for determining, under most circumstances, when incidents are likely to be notifiable. The notification guidelines are given in Table 1 and are intended to be applied to a measurement that is broadly representative of patient exposure. To use the guidelines the ratio of the suspected exposure to the intended exposure must be determined and compared with the appropriate factor in the table. If the suspected exposure was greater than the intended exposure by at least the factor shown, then HSE should be notified of the incident.

Table 1 Guidelines for notification of incidents involving radiation equipment used for medical exposure

Type of diagnostic examination	*Guideline multiplying factor*
Barium enemas, barium meals, IVUs, angiography and other such procedures involving fluoroscopy (including digital radiology) and computed tomography	3
Nuclear medicine: intended E>5 mSv, eg ^{201}T1 (myocardial imaging)	3
Lumbar spine, abdomen, pelvis, mammography and all other examinations not referred to elsewhere in this table	10
Nuclear medicine: intended E< 5 mSv but >0.5 mSv, eg ^{99m}Tc (MAA lung imaging)	10
Extremities, skull, chest, dental examinations and other simple examinations such as elbow, knee and shoulder	20
Nuclear medicine intended E < 0.5 mSv, e.g. ^{51} Cr (EDTA) GFR measurement	20
Type of Treatment	*Guideline multiplying factor*
Beam therapy, brachytherapy	1.1 (whole course) or 1.2 (any fraction)
Radionuclide therapy, eg ^{131} 1	1.2 (any administration)
NOTE: E is effective dose	

The majority of exposures much greater than intended that are reported to HSE involve diagnostic radiology equipment. In many cases the fault cannot be replicated, either by the employer or the manufacturer's service engineers, and equipment is put back into use without the cause of the incident being identified. The employer should make an assessment of the likelihood and consequences of recurrence before putting equipment back into use. HSE's investigations of such incidents have usually resulted in actions being required of the equipment manufacturer as well as the employer.

HSE is revising its guidance on the requirements relating to equipment used for medical exposures. The revised document[3] will contain more specific guidance on the co-operation between employers and manufacturers of equipment, in relation to the provision of information, and liaison between service engineers and the employer's representatives.

7. ENFORCEMENT

Earlier paragraphs have identified poor standards of radiation protection and failure to comply with IRR99. The majority of inspections and investigations point to a lack of suitable and sufficient risk assessments for the work with ionising radiation and inadequate training and instruction as major contributing factors.

The HSE is currently carrying out audits in a selection of hospitals in Great Britain to determine the standards of radiation protection and level of compliance with IRR99 two years after their introduction. This will give a comprehensive picture of the current situation in the part of the medical sector that is responsible for the majority of employee and patient doses. The results of the audit will assist HSE in the targeting of future inspections.

8. CONCLUSIONS

There has been legislation in place in Great Britain for the control of work with ionising radiation since 1985. Despite this, compliance in the medical sector with IRR99 falls far short of the expected standard. HSE intends to take action to address the shortcomings through:

- Inspection of workplaces and investigation of notified incidents;
- Production of further guidance where such a need is identified;
- Liaison with stakeholders including employers, professional bodies and other regulatory authorities such as the Health Departments; and
- Appropriate enforcement action where necessary.

9. REFERENCES

1. Work with Ionising Radiation: Ionising Radiations Regulations 1999: Approved Code of Practice and Guidance [L121] HSE Books 2000
   ISBN 0-7176-1746-7
2. Fitness of equipment used for medical exposure to ionising radiation PM77 HSE Books 1998
   ISBN 0-7176-1482-4
3. Equipment used for medical exposure HSG226 – publication 2002/3 [will replace PM77]