

# **NOTES ON THE IONISING RADIATION REGULATIONS 1999 (IRR 99) (STATUTORY INSTRUMENT 1999 No 3232)**

## **Introduction**

These regulations are a revision to the Ionising Radiation Regulations 1985 and came into force on 1<sup>st</sup> January 2000. There is a supporting Approved Code of Practice with, for the first time, much guidance as well. The 1988 Guidance Notes for the Protection of Persons Against Ionising Radiation arising from Medical and Dental Use are being revised and are expected during 2001. There is rather more supporting information than there was before: a number of new leaflets on different aspects of the regulations have been prepared, the HSE Guidance Note PM77 on Fitness of Equipment used for Medical Exposure to Ionising Radiation is being revised and the HSE website (<http://www.open.gov.uk/hse/hsehome.htm>) is to be a prime vehicle for information about the Regulations. Similar regulations are in force in Scotland and Northern Ireland.

## **Why Revise the Regulations?**

The Regulations have been revised because of the publication of the International Commission on Radiological Protection Report 60 in 1991, which introduced revised radiation estimates. This caused the European Commission to revise its Basic Safety Standards (BSS) Directive (96/22 Euratom) and the Medical Exposure Directive (97/43/Euratom). European member states had until May 2000 to implement these new directives. The Ionising Radiation Regulations 1999 and the Ionising Radiation (Medical Exposure) Regulations 2000 (which replace the 1988 POPUMET Regulations) implement most of the changes, with the remainder being covered by other legislation such as the Radioactive Substances Act 1993 (also under revision) and the Medicines (Administration of Radioactive Substances) Regulations. Another reason for the revision is to absorb other legislation, such as the Outside Worker's Regulations in line with Government policy to reduce the amount of health and safety legislation. One issue not yet covered by the new legislation is justification and a free standing Regulation on this is expected.

## **What has changed?**

The short answer is that not much has changed. Some of the main revisions are listed below. These brief notes are not exhaustive.

- Structure

The Regulations have been reorganised into a more logical sequence, comprising seven parts and nine schedules. The parts are:

- Interpretation and General
- General Principles and Procedures
- Arrangements for the Management of Radiation Protection
- Designated Areas
- Classification and Monitoring of Persons
- Arrangements for the Control of Radioactive Substances, Articles and Equipment
- Duties of Employees and Miscellaneous

- Terminology

There are some revisions. The Employer now becomes "Radiation Employer" to make it clearer and this is an Employer who in the course of a trade, business or other undertaking carries out work with Ionising Radiation. Dose constraint is introduced which is a restriction on the prospective dose to individuals which may

result from a defined source and the “dose” quantity now used throughout is effective dose rather than effective dose equivalent.

- Prior Risk Assessment

This is required for new activities not fully covered by an existing risk assessment. Under Regulation 3 of the Management of Health and Safety at Work etc Regulations 1999, a suitable and sufficient risk assessment has been required for all work activities. The new Regulations specifically require a risk assessment for work with ionising radiation. Therefore new activities require a prior risk assessment and as do existing activities if an assessment does not exist.

- Prior Authorisation

This comes directly from the BSS Directive, e.g. X-ray sets used for industrial radiography, the processing of products, research or medical treatment (not diagnosis) and accelerators require prior notification to HSE. However, generic authorisations have been developed which will mean that effectively the majority of users do not have to take any action.

- Notification to HSE

There has always been a requirement to notify HSE before commencing work with ionising radiation for the first time. This is essentially unchanged.

- Radiation Protection Adviser (RPA)

There are stricter controls on who can act as an RPA and certain core competencies have to be achieved. Individuals will have to have a certificate from a recognised assessing body and RPA bodies (previously Corporate RPAs) will have to be recognised by the HSE. It is left to the Radiation Employer to determine whether the RPA's qualifications are suitable for the work, which the employer wants the RPA to do. There are also some changes about when to appoint an RPA. Essentially an employer has to consult an RPA on the Regulations, but only has to appoint the RPA if as a result of the consultation it is necessary. Appointments should state the scope of advice to be given. This will not materially affect the appointment of RPAs in hospitals.

- Qualified Person

The Employer no longer has to notify the HSE about the appointment of the Qualified Person who is appointed to calibrate radiation detectors.

- Restricting Exposure

This is largely the same as in the present Regulations, with full use of the ALARP (as low as reasonably practicable) principle. Maintenance of engineering controls to restrict radiation exposure is now explicitly required and dose constraints are introduced. These are unlikely to be needed, except when applied to a Comforter or Carer. This is an individual who (other than as part of his/her occupation) knowingly and willingly incurs an exposure to ionising radiation resulting from the support and comfort of another person who is undergoing, or who has undergone, any medical exposure. This category has been introduced to avoid problems in applying dose limits to people who are essentially members of the public, but who may well receive doses in excess of the new dose limits when voluntarily looking after a relative, e.g. a parent looking after a child undergoing radiation treatment.

- Female Workers

Employers now have to assess the risks for pregnant and breast feeding women (see Risk Assessment earlier) and if necessary review and revise working conditions. They also have to provide advice to employees who may be pregnant and consider the risk of contamination in women who are breast feeding. A new requirement on employees is that they have to declare their pregnancy or that they are breast feeding in writing and the employer's responsibilities do not commence until they have done so.

- Dose Limits

The whole body dose limit for adult employees has reduced to 20mSv per year effective dose. Averaging over 5 years is allowed, only in very special cases so that an employee may receive up to 50mSv in one year, provided that the average over 5 years does not exceed 20mSv. Other dose limits are in the table. Eye and extremity dose limits are unchanged but the averaging area for skin dose is reduced by 100.

<b>ANNUAL DOSE LIMITS</b>			
	Adult >18y	Trainee <18y	Other persons including <16y
Whole body	20	6	1
Lens of eye	150	50	15
Skin (averaged over 1cm <sup>2</sup> )	500	150	50
Hands, forearms, feet and ankles	500	150	50
Women of reproductive capacity – dose throughout abdomen: <13mSv in any consecutive 3 month period			
Conditions of exposure to foetus of woman who has notified employer of pregnancy: unlikely to exceed 1 mSv for remainder of pregnancy N.B.: This is not a “dose limit”			
Conditions of exposure of breast feeding employees are restricted so as to prevent significant bodily contamination.			

- Classified Persons

Designation is now necessary for employees who are likely to receive an effective dose in excess of 6mSv per year whole body dose. This is unlikely to cause any change in the number of classified persons in hospitals. The levels for classification on the basis of eye dose or extremity dose are unchanged.

- Controlled and Supervised Areas

In general, there will be no need to change controlled and supervised areas, although the rationale for controlling areas has changed. Previously, it was linked to the dose rates and the likelihood of staff receiving doses in excess of 3/10ths of a relevant dose limit. In the new Regulations, the employer has to control an area because of the need to apply special procedures, e.g. controlling access to an x-ray room. In other words, flexibility has been built in. There is a new requirement for warning signs to state the risk that the warning sign is referring to, e.g. risk of contamination, x-rays etc. Warning signs are no longer essential for supervised areas.

- Local Rules

There is a change here, in that previously Local Rules were written for any work activity involving radiation, whereas now the requirement is to have Local Rules for work in controlled and supervised areas. In practice, this makes little difference and the content of the Local Rules is broadly similar. HSE have emphasised that the rules should be concise and reference may be made to other documents that contain more detailed information. All Local Rules supplied by RPC will have to be edited to reflect the new Regulations. The term "System of Work" has been dropped.

- Radiation Protection Supervisor (RPS)

The change here is that the RPS must be suitable and because not every employer has a suitable RPS on the staff, it is no longer essential for the person to be an employee.

- Medical Exposure

Medical Exposure means exposure of a person to ionising radiation for the purpose of his/her medical or dental examination or treatment which is conducted under the direction of a suitably qualified person and includes any such examination for legal purposes and any such examination or treatment conducted for the purposes of research. The only change in the definition is that it now covers examination for legal purposes. As in the current Regulations, there is a requirement for equipment to be designed, constructed, installed and maintained so as to be capable of restricting exposure, so far as is reasonably practicable, compatible with the intended clinical purpose or research objective. The main difference is that Quality Assurance, although implicit in the 1985 Regulations, is now explicitly required and that equipment must be tested before first use and periodically thereafter and after any major maintenance procedure. There is also a requirement for measurements at suitable intervals to enable the assessment of representative patient doses.

The requirement to inform HSE about faults which result in a patient being exposed to a much greater extent than intended is unchanged.

There is a new requirement to ensure that newly installed equipment has a suitable means for indicating the quantity of radiation produced during a radiological procedure. The revised Guidance Note PM77 will give more information about procedures for accepting equipment back into service after major repair.

#### Critical Examination

The change here is that the RPA longer has to be present for the critical examination but has to be consulted about the nature and extent of the examination and about the results. The full text of Regulations 31 and 32 on duties of manufacturers etc and equipment used for medical exposures and the associated approved code and guidance is attached.

### **Summary**

The introduction of IRR99 will require you to review your current control measures. However, HSE's view is that if you are already complying with IRR85 and the Management of Health & Safety at Work Regulations 1999, this review should show that there is little more you need to do to satisfy the objectives of IRR99.