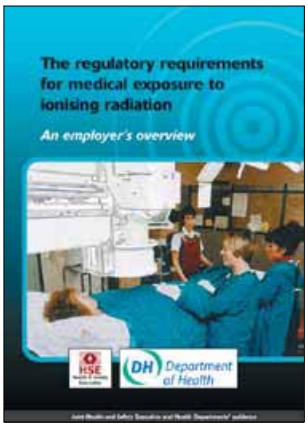
The regulatory requirements for medical exposure to ionising radiation

An employer's overview



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The purpose of this guidance is to provide you with an overview of your responsibilities under ionising radiation protection regulations. These regulations require you, as an employer, to manage use of radiation in the workplace.

The guidance is aimed at senior managers, including Directors and clinicians, within the medical sector. This includes Chief Executives of hospitals in the NHS and private sector, as well as other medical users of ionising radiation, such as chiropractors and dentists.

Additionally, the guidance will also be useful to those senior managers in the medical sector who are responsible for health and safety or risk management.

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This guidance is issued by the Health and Safety Executive. Following the guidance is not compulsory and you are free to take other action. But if you do follow the guidance you will normally be doing enough to comply with the law. Health and safety inspectors seek to secure compliance with the law and may refer to this guidance as illustrating good practice.

Contents

Who is this guidance aimed at?

1 This guidance is aimed at senior managers, including Directors, and clinicians, within the medical sector. This includes Chief Executives of hospitals in the NHS and private sector, as well as other medical users of ionising radiation, such as chiropractors and dentists. The guidance will also be useful to those senior employees in the medical sector who are responsible for health and safety or risk management.

What is the purpose of the guidance?

2 The purpose of this guidance is to provide you with an overview of your responsibilities under ionising radiation protection regulations which require you, as an employer, to manage the use of radiation in the workplace (see Appendix 2 for more detailed guidance).

3 The regulations include the Ionising Radiations Regulations 1999 (IRR99) and the Ionising Radiation (Medical Exposure) Regulations 2000 (IR(ME)R2000). The Health and Safety Executive is responsible for IRR99 and the Health Departments in England, Scotland and Wales are responsible for IR(ME)R2000.

In Northern Ireland, the equivalent regulations are the Ionising Radiations Regulations (Northern Ireland) 2000 (IRR(NI)2000) and the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2000 (IR(ME)R(NI)2000). These Regulations are essentially the same as the legislation in Great Britain and the guidance given in this document can be taken as equally applying to Northern Ireland. The Health and Safety Executive for Northern Ireland is the responsible authority for IRR(NI)2000 and the Department of Health, Social Services and Public Safety (Northern Ireland) is responsible for IR(ME)R(NI)2000.

4 Together, the Regulations require you, as an employer, to manage the radiation protection of patients, employees, patients' families, the general public, and indeed of yourself. You now have specific legal duties to create a framework under which professionals can practice safely.

5 It is not the purpose of this guidance to provide detailed requirements for protection of employees or the management of radioactive medicinal products. Advice on these matters may be obtained from your Radiation Protection Adviser (RPA) and may be found in:

- *Work with ionising radiation. Ionising Radiations Regulations 1999. Approved Code of Practice and guidance* (see Appendix 2);
- IR(ME)R guidance (see Appendix 2).

In Northern Ireland this code of practice has been adopted and approved by the Health and Safety Executive for Northern Ireland, for use with IRR(NI)2000.

Which employers are covered?

6 Both IRR99 and IR(ME)R2000 apply to any employer who uses ionising radiation for medical purposes. This means any employer who undertakes medical exposures (eg diagnostic imaging, unsealed radioisotopes, nuclear medicine, radiotherapy etc). It also applies to employers whose employees carry out medical exposures, or provide health care for patients who have been administered radioactive medicinal products.

Why do I need to read it?

7 Chief Executives, Directors and line managers have clearly defined responsibility for health and safety under the Health and Safety at Work etc Act 1974 (HSW Act). Both IRR99 and IR(ME)R2000 are enforced under the HSW Act. Because employers have an important role under both sets of Regulations, you will need to be aware of your responsibilities and accountability.

In Northern Ireland the equivalent legislation to the Health and Safety at Work etc Act 1974 is the Health and Safety at Work (Northern Ireland) Order 1978.

8 This accountability under the HSW Act **cannot be delegated** to anyone else in your organisation. Although you may employ others to produce the policies and procedures which need to be implemented in your workplace, you, as the employer, remain responsible in law for making sure these are in place. If you do not effectively manage the safe use of ionising radiation in the workplace, then both the Health and Safety Executive and the Health Departments have a range of enforcement options available to them, depending on the seriousness of the offence. This range includes issuing enforcement notices and prosecution for breaches of the legislation. Prosecution can involve imprisonment and/or fines. So it makes sense to make sure your workplace has a framework for radiation protection which effectively manages and controls the risk to both employees and patients.

What does managing the risk mean?

9 You are obliged under the Management of Health and Safety at Work Regulations 1999 (MHSWR) to assess workplace risks to your employees and others who may be affected by the work in your organisation, in this case patients, their families and friends, and the general public.

In Northern Ireland the equivalent regulations are the Management of Health and Safety (Northern Ireland) Regulations 2000.

10 Before you start any new work activity that involves the use of ionising radiation, IRR99 requires you to assess the risk and identify suitable measures which restrict exposure to that risk. However, managing the use of ionising radiation is no different from managing any other health and safety risk. You will need to review your risk assessment periodically to ensure that the arrangements you have in place for controlling the risk remain effective. This will need to be documented.

11 MHSWR also sets out general principles for prevention which provide a hierarchy for eliminating or controlling the risk in the workplace. Generally, avoid the risk where practicable. However, the benefits of diagnostic and therapeutic procedures using ionising radiation are well recognised in health care of patients. IRR99 and IR(ME)R2000 set out a framework which emphasises the need to restrict the risk so far as reasonably practicable, and for medical purposes this should be consistent with the intended clinical outcome. Each medical exposure must be justified, and it is your responsibility, as the employer, to clearly identify who will undertake this task. This person is known as the ‘practitioner’ under IR(ME)R2000. They must be adequately and appropriately trained for this role.

What role does clinical governance play in this?

12 Clinical governance is the linchpin of the delivery of high quality health care. IRR99 and IR(ME)R2000 fit in well with this concept by helping to create an environment which minimises risks from ionising radiation for people who need to undergo medical exposures to ionising radiation. This is achieved by creating a framework within which appropriately trained and experienced professionals can make sure patients are exposed to radiation doses that are as low as reasonably practicable and consistent with the intended clinical outcome. Clinical governance is concerned with the delivery of high quality health care and its continuous improvement.

What are my responsibilities under the Regulations?

13 The principles of radiation protection are that:

- medical exposure to ionising radiation should only be carried out if it is justified; and
- the level of exposure must be restricted so far as is reasonably practicable in line with the intended clinical purpose.

14 These principles must form the basis of your policy on radiation protection. For example, IRR99 requires you to make sure the equipment used is designed, constructed, installed and maintained to restrict exposure. This applies both to equipment that emits radiation and other equipment that could directly affect the patient dose. This includes the calibration of gamma cameras. It is important for the protection of both employees and patients that excessive exposures are avoided. Equipment selected must be appropriate and used properly for any specific task. Faulty equipment must be quickly identified and taken out of use. IR(ME)R2000 requires you to have procedures to ensure the safe, effective and efficient use of ionising radiation in medical exposures. It also requires that people involved in undertaking these exposures are adequately trained in the work they perform.

15 In addition to the protection of patients, you have responsibilities under IRR99 for the protection of your employees and yourself; for members of the public including the families of patients; and for the safe management of radioactive medicinal products. If patients receive radioactive medicinal products at your hospital (or perhaps at another centre), you will need to consider procedures for managing the risks they may consequently pose for your employees, other patients and members of the public including families of patients and hospital visitors.

What does this involve?

16 You are responsible for the medical exposure aspects of IRR99 and IR(ME)R 2000 in the following five key areas:

- general procedures;
- policy on medical equipment;
- quality assurance programmes;
- training of employees; and
- dealing with incidents.

Where can I obtain further advice?

17 Both IRR99 and IR(ME)R2000 require you to seek advice if you use ionising radiation in your workplace, from the radiation protection adviser (RPA) and the medical physics expert (MPE). However, the responsibility rests with you as an employer. Many hospitals have a Radiation Protection Committee, which might include risk managers, RPAs, radiation protection supervisors, MPEs, other medical physicists, radiographers, radiologists, oncologists, and other clinicians using ionising radiation. The committees serve as useful forums for planning action on these issues.

18 Appendix 1 sets out a summary of your responsibilities relating to the five key areas listed in paragraph 16.

Appendix 1: Key medical aspects of IRR99 and IR(ME)R2000

General procedures

Risk assessment (IRR99 and MHSWR)

1 The risk assessment will be the foundation of any framework for restricting exposure. This is because it will help to evaluate the risks from a particular radiological practice and identify suitable measures for controlling and restricting the risk. This includes considering which engineering controls or design features may be needed, as well as maintenance and quality assurance requirements. You must provide adequate risk assessments for all procedures involving potential exposure to ionising radiation. Where appropriate, these should include a contingency plan dealing with radiation accidents, for example accidental spillages of unsealed radioactive materials in nuclear medicine departments or accidents involving sealed radioactive sources in radiotherapy departments.

Co-operation (IRR99 and IR(ME)R2000)

2 It is very important that where employees either share a workplace or a piece of medical equipment, their employers co-operate with each other. The aim is to co-ordinate any action that might be needed to control the risks and restrict unnecessary exposure. Within IR(ME)R2000 there is also a need for co-operation between the people responsible for the actual medical exposure.

Consultation with experts (IRR99 and IR(ME)R2000)

3 You will need to consult with both RPAs and MPEs for the purpose of complying with IRR99 and IR(ME)R2000. One person may be able to fulfil both roles, providing they are competent to do so.

4 You will need to seek advice from your RPA on plans for installing any new equipment; for accepting it into service; for the maintenance of any existing equipment or when planning new facilities or new activities involving ionising radiation. This includes the quality assurance programmes. The RPA that you consult/appoint must meet the HSE Criteria of Competence (see Appendix 2) to be suitable to provide the advice on your use of ionising radiation (unless they qualify under the transitional arrangements that permit individuals or organisations that have held an RPA appointment under the Ionising Radiations Regulations 1985 to continue to be accepted as RPAs until the end of 2004). The RPA must have current knowledge and experience of the type of radiation work you undertake.

5 The MPE is expected to undertake such tasks as giving advice on patient doses and the use and development of new techniques. Under IR(ME)R2000, you are obliged to ensure that an MPE is involved, as appropriate, to varying degrees in all medical exposures. The amount of involvement is determined by the level of hazard and risk associated with the medical exposure.

Comforters and carers

6 These are defined as people, other than employees, who knowingly and willingly incur an exposure to ionising radiation in support and comfort of a patient. They can, for example, be a friend or relative of the patient. IRR99 requires you to provide suitable information to people choosing to act as comforters and carers on the risks from any indirect exposure to ionising radiation. This information needs to be clear and simple, so that they can make an informed decision on whether they accept those risks. It can be given either directly to the comforter or carer or, in the case of a patient being administered with a radiopharmaceutical, through the patient themselves. The amount of information needed will depend on the likelihood and severity of the risk.

Written operating procedures (IR(ME)R2000)

7 As the employer, you are required to ensure that written procedures for medical exposures, including the procedures set out in Schedule 1 to the Regulations, are in place. This creates a framework in which professionals can practise. Examples of the written procedures include:

- a range of procedures to correctly identify the people entitled to act as specific duty-holders (ie practitioners, operators and referrers) under IR(ME)R2000;
- procedures for recording a clinical evaluation of the outcome of each medical exposure; and
- procedures to be observed in the case of medico-legal exposures.

8 You may ask another person to produce the procedures but you remain responsible in law for them being in place. You must also take steps to ensure that duty holders under IR(ME)R2000 comply with them. If you are an employer in a small practice and also undertake some or all of the functions associated with the other duty holders, you are still responsible for ensuring procedures are in place.

Written protocols (IR(ME)R2000)

9 You are responsible for ensuring that written protocols are in place for every type of standard radiological practice, for each piece of equipment. These are quite different from the procedures referred to above. These protocols relate to the technical aspects required for exposures for standard examinations or treatments on each piece of equipment and may allow latitude for professional judgement.

Referral criteria (IR(ME)R2000)

10 You are responsible for establishing recommendations concerning referral criteria, which include radiation doses. These criteria should be agreed locally with professionals involved in medical exposures and must be made available to everyone who refers patients for medical exposures to your department. There is an obligation to produce these criteria, regardless of the size or type of department and irrespective of situations where you act as the employer and referrer and are involved in the process of the medical exposure itself.

Diagnostic reference levels (IR(ME)R2000)

11 Diagnostic reference levels (DRLs) relate to the radiation dose to the patient and you are required to establish these for typical examinations. This includes standard radiological investigations, interventional procedures and nuclear investigations. When setting your DRLs (probably with the assistance of your Radiation Protection or Medical Exposures Committees), you must pay due regard to European and national levels, as well as local information on the magnitudes of typical exposures within your organisation. You are also obliged to review your DRLs regularly. If your DRLs are consistently exceeded, you must ensure that corrective action is taken. This might include setting new values for the DRLs or might involve modifying equipment, changing techniques or retraining an employee.

Research (IR(ME)R2000)

12 Research is included in the range of exposures covered by these Regulations. All exposures made as part of medical or biomedical, diagnostic or therapeutic research must first be approved by a Local Research Ethics Committee or the equivalent in Northern Ireland. There are specific obligations placed on you by IR(ME)R2000 for these exposures. These include having procedures to ensure that people participate voluntarily in the research programme and are informed in advance of the risks of the exposure. For those people for whom no direct health benefit is expected, your procedures must set down a dose constraint which must be adhered to. Where someone is expected to receive a diagnostic or therapeutic benefit, individual target levels for doses must be planned by the person who justifies the exposure, to avoid excessive doses of radiation.

Policy on medical equipment (IRR99)

13 Procurement, the provision of the appropriate equipment, will be fundamental in restricting exposures to patients. The term 'appropriate equipment' means all equipment used in connection with a medical exposure, including related ancillary equipment such as film cassettes and isotope calibrators, which can affect the likelihood of an excessive exposure to a patient. IRR99 requires you to ensure that the equipment is designed, constructed, installed and maintained so that it is capable of restricting exposure in line with the intended clinical purpose. You will also need to co-operate and consult with other employers if there are proposals to obtain equipment through Public Private Partnerships or an equivalent. This will involve sharing information on:

- the suitability of the equipment; and
- the maintenance and quality assurance requirements needed to ensure its effectiveness at restricting exposure, in line with the intended clinical purpose. This is to ensure that the equipment is in good working order.

Installation and maintenance

14 Before you install new equipment or new facilities or begin new activities involving ionising radiation, you must consult your RPA about the plans. When new equipment is first installed, the installer must do a critical examination to ensure that the equipment has been safely installed. The installer must involve their RPA or, with your agreement, your RPA. The equipment, once installed, will need to be tested before first use and be subject to a planned maintenance programme. This will ensure that it is in good working order and repair and is capable of restricting exposure to as low as reasonably practicable. At this stage, you must again involve your RPA. If equipment is shared by a number of employees, it is important that information is provided to everyone who uses it, particularly information on what to do if there is a fault or problem.

Quality assurance programmes

Equipment (IRR99)

15 A quality assurance programme is necessary, in addition to the maintenance programme. A suitable quality assurance programme for equipment is one that establishes those planned and systematic actions necessary to provide adequate confidence that all medical equipment:

- is capable of restricting exposure; and
- will continue to restrict exposure; and
- is consistent with the intended clinical purposes.

The quality assurance programme will go further than the basic maintenance programme, because it should look at the level and type of equipment and how it will be used. For all new equipment it is important that, on installation, you have considered the quality assurance requirements, particularly the need for periodic testing. The programme should also identify the frequency of testing and who is responsible for it. Your RPA should be consulted in designing and implementing the programme.

Equipment (IR(ME)R2000)

16 You must keep an up-to-date inventory of the equipment used for medical exposures and make this available on request to officials acting on behalf of the Department of Health in England or, if your installation is in Scotland, Wales or Northern Ireland, the appropriate Health Department. The inventory must include the name of the manufacturer, model number, serial number, year of manufacture and year of installation. You are also required to ensure that the amount of equipment in your departments is limited to that necessary for the proper carrying out of medical exposures.

Procedures (IR(ME)R2000)

17 You must have a quality assurance programme for your written procedures. These procedures should be regularly reviewed to ensure that they are effective and appropriate and to identify any necessary amendments.

18 The objective of quality assurance, both for the equipment and procedures, is the same, ie restricting exposure to as low as reasonably practicable, compatible with the intended clinical purpose.

Training of employees

19 IRR99 requires that all employees engaged in work with ionising radiation be given adequate and appropriate radiation protection training. The information, instruction and training is intended to ensure they are aware of the risks to both themselves and others, including patients.

20 IR(ME)R2000 requires you to ensure that practitioners and operators involved with a medical exposure are adequately trained for the functions they undertake. There is also an obligation on them not to undertake any duty without being adequately trained in it. You must keep an up-to-date record of your employees, showing the nature of their training and the date it was completed. These records must be kept separately from general personnel records and be available on request. If you engage an individual who is employed by another body, eg an agency, then that body is responsible for keeping and maintaining these records and must make them available to you on request. You are required to ensure that the practitioner and the operator also receive continuing education and training after qualification. This will include training related to new techniques, radiation protection etc.

Dealing with incidents

21 IRR99 requires you to report and investigate incidents which lead to overexposure of employees or excessive exposure of patients as a result of equipment malfunction or failure. For example, if a piece of equipment, because of either a malfunction or defect, exposes a patient to an extent much greater than intended, you must undertake an investigation to establish what happened and why, to prevent a recurrence. You must report the incident to the Health and Safety Executive and in Northern Ireland to the Health and Safety Executive for Northern Ireland. The RPA can advise you on what is a reportable incident. See also *Fitness of equipment used for medical exposure to ionising radiation* (see Appendix 2 for details).

22 IR(ME)R2000 requires you to make a similar investigation of incidents, where it is suspected that a patient may have received a radiation dose much greater than intended, while undergoing a medical exposure, other than as a result of equipment defect or failure. You must report the incident to the appropriate authority, which in England is the Secretary of State's Inspectorate at the Department of Health. If the incident has occurred in Scotland, Wales or Northern Ireland, you must report it to the appropriate Health Department. Your investigation should establish what has happened, identify any failure, decide on remedial action to minimise the chance of a similar event and estimate the dose received. Department of Health guidance on the reporting of such incidents is to be published shortly.

23 This summary represents a brief overview of your key duties in relation to medical exposure under the Regulations. It is not a full account of all the requirements of IRR99 or IR(ME)R2000. Further information is given in the guidance supporting IRR99 and IR(ME)R2000 (see Appendix 2 for further details).

Appendix 2: Other useful information and guidance

Fitness of equipment used for medical exposure to ionising radiation PM77 (Second edition) HSE Books 1998 ISBN 0 7176 1482 4

Five steps to risk assessment INDG163(rev1) HSE Books 1998 (single copy free or priced packs of 10 ISBN 0 7176 1565 0)

Guidance on the protection of people against ionising radiations from medical and dental use is in preparation and will be published by the Institute of Physics and Engineering in Medicine. For further details, phone 020 7717 6832.

The HSE Criteria of Competence is contained in the *HSE statement on Radiation Protection Advisers* at www.hse.gov.uk/hthdir/noframes/state.htm

Ionising Radiation (Medical Exposure) Regulations 2000 SI2000/1059 The Stationery Office 2000 ISBN 0 11 099131 1

Ionising Radiation (Medical Exposure) Regulations 2000: Notes on good practice www.doh.gov.uk/irmer.htm

Management of health and safety at work. Management of Health and Safety at Work Regulations 1999. Approved Code of Practice and guidance L21 (Second edition) HSE Books 2000 ISBN 0 7176 2488 9

Management of health and safety in the health services: Information for directors and managers Health Services Advisory Committee HSE Books 1994 ISBN 0 7176 0844 1

'Patients leaving hospital after administration of radioactive substances' *The British Journal of Radiology* **72** (1999) 121-125 (The British Institute of Radiology guidance on written instructions to patients)

Successful health and safety management HSG65 (Second edition) HSE Books 1997 ISBN 0 7176 1276 7

Work with ionising radiation. Ionising Radiations Regulations 1999. Approved Code of Practice and guidance L121 HSE Books 2000 ISBN 0 7176 1746 7

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