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Equipment used in connection with medical exposure

Guidance Note **PM77** (Third edition)

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.

Introduction

1 The advice in this guidance note is for employers who have to any extent control of equipment used in connection with medical exposure to ionising radiation. This includes many NHS employers and private healthcare providers, medical x-ray services in industry, dentists, physiotherapists, osteopaths and chiropractors (this list may not be exhaustive). It may also include companies involved in providing facilities under Private Finance Initiative Schemes (PFI). The guidance will be useful to radiation protection advisers (RPAs) who have been consulted by such employers.

2 Advice is given on compliance with the Ionising Radiations Regulations 1999¹ (IRR99) in relation to equipment used in connection with medical exposure. In particular the guidance provides advice on the requirements of IRR99 Regulation 32(1), ie that the employer ensures **equipment is of such design or construction and is so installed and maintained as to be capable of restricting so far as is reasonably practicable the exposure to ionising radiation of any person who is undergoing a medical exposure to the extent that it is compatible with the intended clinical purpose or research objective**. The advice does not cover duties under the Ionising Radiation (Medical Exposure) Regulations 2000 (IR(ME)R)² but references are made to those Regulations where appropriate in the context.

Guidance Notes are published under five subject headings:

Medical
Environmental Hygiene
Chemical Safety
Plant and Machinery
General

3 'Medical exposure' is defined in IRR99 regulation 2(1) as *'exposure of a person to ionising radiation for the purpose of his 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.'* For simplicity, all persons undergoing medical exposures are referred to as 'patients' in this guidance.

4 This guidance supplements the general advice on compliance with IRR99 that can be found in *Work with Ionising Radiation. Ionising Radiations Regulations 1999 Approved Code of Practice and Guidance L121*.³

Scope

5 This guidance includes advice on:

- the selection, installation, maintenance, calibration and replacement of equipment;
- criteria of acceptability for both new and older equipment;
- quality assurance programmes, including adoption of suspension levels;* and
- the investigation of incidents involving a malfunction or defect in radiation equipment which results in an exposure much greater than intended.

* Suspension Level is the level of non-compliance with quality assurance criteria at which an item of equipment should be removed from clinical use with immediate effect. For example, recommended levels for the suspension of diagnostic X-ray equipment are published in IPEM publication No. 77¹⁶

6 'Equipment used in connection with medical exposure' includes all equipment whose design, construction, installation or maintenance (and any fault that might develop in it) can affect the magnitude or distribution of the absorbed dose received by the person undergoing a medical exposure. It includes:

- equipment intended to be used in connection with diagnostic or therapeutic procedures using ionising radiation and interventional radiology;
- radiation equipment (as defined by IRR99 regulation 32(8) and in paragraph 7); and
- ancillary equipment such as intensifying screens, computed radiography (CR) plates, CR readers, cassettes, digital fluorography systems, couches, anti-scatter grids, beam modifiers (eg filters and wedges), gamma cameras, computerised radiotherapy treatment planning systems and film processing units.

7 For the purpose of IRR99 regulation 32(5-8) 'radiation equipment' means equipment which delivers ionising radiation to the person undergoing medical exposure and equipment which directly controls the extent of the exposure. Such equipment would include X-ray tubes, AEC devices (including image intensifiers), beam collimators, direct digital radiography systems, radiotherapy treatment machines and radionuclide dose calibrators. The section 'Exposures greater than intended' relates solely to radiation equipment.

8 Employers should be aware that technology evolves and equipment design and specification may change significantly. Procedures and associated programmes should therefore be reviewed regularly to ensure they remain relevant to any new equipment and in compliance with IRR99 regulation 32.

9 This guidance applies to new and second-hand equipment and to equipment under loan (including for demonstration purposes, where that equipment is used in connection with medical exposures).

General duties of employers under IRR99

10 The employers referred to in the introduction are defined as 'radiation employers' in IRR99 regulation 2(1), as they either work or intend to work with ionising radiation. For simplicity, these are referred to as employers throughout the rest of this document. Such employers have a number of duties under IRR99 in

relation to employees and members of the public. These are discussed in detail in L121.³ Employers must comply with aspects of IRR99 which apply to exposure to ionising radiation of employees and other persons (other than those undergoing medical exposure).

Co-operation between employers

11 Employers who either share a workplace or an item of equipment used in connection with medical exposures, must co-operate with each other regarding the control of associated risks and compliance with IRR99 (and other relevant legislation). This means sharing information on the types of exposure for which the equipment is suitable, and the maintenance and quality assurance requirements needed to ensure its effectiveness at restricting exposure. If there are any modifications to the equipment, or new equipment is brought into service, the employer who authorises the modifications or new equipment should immediately inform other employers who use the equipment of the changes, and ensure that they are aware of anything that may affect the health and safety of the staff or the patient (see paragraphs 241-247 of L121³).

12 There may be situations in which employers are in control of premises where equipment is used in connection with medical exposures, but do not have specific responsibility for that equipment. Examples include companies owning premises where equipment that has been purchased or leased under public-private partnership schemes (or private finance initiative schemes), is used by another employer. In such situations it is essential that all employers co-operate to comply with IRR99 and to provide adequate information on associated risks. The detailed arrangements for co-operation and their periodic review should be agreed at the contract stage. It should be noted that the duties of IRR99 regulation 32 are placed on employers who have to any extent control over equipment used in medical exposures.

Duties of manufacturers, suppliers, installers and erectors of articles for use in work with ionising radiation

Design and construction

13 IRR99 regulation 31(1) extends the duties under Section 6 of the Health and Safety at Work etc Act 1974⁴ (HSWA), so that there is a duty on manufacturers, importers and suppliers to ensure that any article for use with ionising radiation is so designed and constructed to restrict, so far as is reasonably practicable, the exposures of persons to ionising radiation arising out of its use. Although this requirement does not apply to the protection of persons undergoing medical exposures, it does apply to the exposure of other persons, including staff that

carry out the exposure and members of the public. As discussed in the section 'Selection of equipment', IRR99 regulation 32(1) requires the employer to consider restriction of patient exposure when purchasing equipment.

14 The manufacturer is responsible for ensuring that their product complies with all the Essential Requirements of Annex 1 of the Medical Devices Directive (MDD) 93/42/EEC,⁵ the Consumer Protection Act,⁶ and the Medical Devices Regulations (MDR) 2002 (SI 2002 No 618).⁷ The MDD is a single market measure designed to remove technical barriers to trade by harmonising safety and performance requirements for medical devices. The CE mark is applied to denote conformity, enabling manufacturers to market their products freely throughout the European Community without having to abide by any further national controls. HSE work closely with the Medicines & Healthcare products Regulatory Agency (MHRA), Scottish Executive Health Department, Welsh Assembly Government, and Department of Health and Social Security (Northern Ireland), to ensure that manufacturers and employers comply with the relevant aspects of both IRR99 and MDR.⁷

Critical examination

15 IRR99 regulation 31(2) requires a person who erects or installs an article for use in work with ionising radiation to:

- where appropriate, undertake a critical examination of the way in which the article was erected or installed;
- consult an RPA with regard to the nature and extent of the critical examination and its results; and
- provide the employer with adequate information about proper use, testing and maintenance of the article.

This regulation does apply to the protection of persons undergoing a medical exposure.

16 A critical examination will be appropriate in cases where there might be radiation protection implications, for either staff or patients, associated with the incorrect installation of the equipment. Examples include the failure of the safety features or warning devices to operate correctly, poor location or inadequate shielding. The requirement applies to:

- installation of equipment (whether new, second-hand or refurbished);
- relocation of existing equipment (including relocation within the same premises); and
- in cases following major service or repair work where there may be radiation protection implications, eg following the fitting of:

- a replacement x-ray tube or automatic exposure controls (AECs) (including to mobile or portable units);
- a klystron on a linear accelerator; or
- an ion chamber on a dose calibrator.

17 The critical examination should include the safety features, warning devices and protection from (unintended) exposure to ionising radiation provided for the protection of the patient. For example, AECs, exposure interlocks, back up timer, light/x-ray beam alignment and shielding from leakage radiation, may come within the scope of the critical examination.

18 Where equipment components arrive on site ready-assembled, the person undertaking the critical examination on site may wish to request the records of assembly from the factory, and any critical examination associated with them. While mobile equipment that is delivered fully assembled does not formally require a critical examination (if erected in the European Union, it should have been critically examined by the manufacturer), employers are advised to check that the safety features are functioning prior to first clinical use, to demonstrate compliance with the requirements of regulation 32(1).

19 Portable equipment, eg that used for domiciliary radiography, should be tested appropriately and consideration given to the extent and suitability of shielding prior to any exposure taking place. The degree of testing, and what constitutes an acceptable result, should be agreed with the RPA prior to the domiciliary visit. It may be useful to use a written protocol for the purpose.

20 While the duty to carry out a critical examination rests with the installer, the RPA consulted may be either the RPA appointed by the installer or the employer's own RPA. The employer and the installer should establish at the contract stage who will carry out the critical examination, ie medical physics staff or the service engineer, and which RPA will take part. The RPA should have the relevant knowledge and experience in order to provide advice in relation to the critical examination. Following a satisfactory outcome to the critical examination, it is in the interests of both parties for the installer to prepare a report, endorsed by the RPA, to confirm that this is the case. It would be prudent to keep this report with the maintenance record of the equipment during its operational life. If the outcome of the critical examination is unsatisfactory, then the failure should be reported to the employer, remedial action taken and the examination repeated. In any event the employer should not bring any equipment into use unless, if appropriate, a critical examination has been satisfactorily completed.

Requirements of IRR99 specific to equipment used in connection with medical exposures: regulation 32

Selection of equipment

21 An employer purchasing or leasing new, second-hand or transferred equipment should be satisfied that it is suitable and appropriate for the medical exposure for which it will be used, including the magnitude and distribution of patient dose. The employer should also consider the extent to which the equipment incorporates safety devices that inhibit operation in the event of a serious fault. At the selection stage the employer should consider the maintenance, servicing and quality assurance testing requirements. Maintenance of equipment is discussed in more detail in paragraph 34 and Appendix 1. The employer may find it helpful to consult the RPA and the medical physics expert (MPE) when selecting equipment to be used in connection with medical exposures.

22 When selecting new equipment (including ancillary equipment), the employer should consider any relevant reports or guidance provided by organisations such as the Radiation Protection Division of the Health Protection Agency (HPA(RPD)), the Institute of Physics and Engineering in Medicine (IPEM), British Institute of Radiology (BIR), National Health Service Breast Screening Programme (NHSBSP), British Nuclear Medicine Society (BNMS) and the Medicines & Healthcare products Regulatory Agency (MHRA) (this list is not exhaustive). For example, the MHRA has issued Medical Electrical Installation Guidance Notes (MEIGaN)⁸ relating to the electrical installation of permanently installed medical devices (diagnostic imaging and radiotherapy installations).

23 Information can be obtained from the following sources:

- Evaluation reports on some new equipment are produced for the NHS Purchasing and Supply Agency (PASA). Evaluation reports published since 2002 are available electronically to download (as pdfs) from the Centre of Evidence-based Purchasing website at www.pasa.nhs.uk/evaluation/publications/ (use the contact details on the website to enquire about less recent evaluations).
- The KCARE programme 'SafeSpecs' is a web application designed to assist in the process of preparing a technical specification which can be sent to X-ray equipment manufacturers (excluding those of CT scanners and X-ray Bone Densitometers). It will also aid in the interpretation of the data supplied, and provide general background information on X-ray equipment technology. SafeSpecs is available free to NHS users, and for a small fee for others, via the

KCARE website (www.kcare.co.uk).

- For CT scanners the ImpACT group can provide equivalent specification, and further information is available on their website (www.impactscan.org).

24 All radiation equipment used for diagnosis installed for the **first** time after 1 January 2000 must, where practicable, be fitted with suitable means to inform the user of the quantity of radiation being produced (regulation 32(2)). Suitable means may include a device which shows the product of X-ray tube current and exposure time or a dose area product (DAP) meter. These devices may not be suitable or sufficient for certain types of equipment, such as dental, mammographic, CT and bone densitometry X-ray equipment, and alternatives should be considered. Examples include devices to display the following parameters:

- exposure time on fixed kV/mA dental X-ray units;
- kV, mAs, target and filter (also compressed breast thickness where available) on mammographic units;
- CTDI on CT scanners; and
- scan time on bone densitometry units.

Installation of equipment

25 The employer should find the installer's critical examination report (see paragraphs 15-20) useful in helping to ensure that the equipment has been properly installed. The employer should bear in mind that the critical examination is not a test of the initial integrity of the equipment but is a check to ensure that safety features and warning devices operate correctly, and that the radiation protection features are adequate. Further tests before use, including image quality, patient dose and electrical and mechanical safety will be required (see paragraphs 26-33).

Quality assurance programmes

26 The employer is required to provide a suitable quality assurance (QA) programme for equipment used in connection with medical exposures (including ancillary equipment), IRR99 regulation 32(3,4). The QA programme must include the following:

- tests on equipment prior to its first clinical use (these tests are separate from those of the critical examination and will probably include acceptance tests (to confirm that the equipment is functioning as intended) and commissioning tests (to determine baseline results against which to compare future measurements and to determine appropriate clinical exposure settings));
- adequate tests of equipment performance at appropriate intervals and after any major maintenance procedure; and
- where appropriate, measurements at suitable intervals to assess patient doses from radiation equipment.

Testing may be carried out by the employer's own staff or by contractors, or both. Aspects of routine testing that may only be carried out by, or with the assistance of, the service engineer, should be agreed at the contract stage, together with the arrangements for test results to be transmitted to the employer without delay. It is the employer's responsibility to ensure that the tests are adequate and that appropriate remedial action is taken where necessary.

27 A suitable QA programme is one that clearly establishes planned and systematic actions necessary to ensure the equipment will satisfy the requirements of IRR99 regulation 32(1). The RPA should be consulted regarding QA programmes for equipment (including ancillary equipment). The extent of the programme will depend on the nature and range of equipment in use. The following should be considered when drawing up and implementing a suitable QA programme:

- advice from the manufacturer, particularly where the normal operating mode of the equipment (for example, some fluoroscopy/fluorography units) does not allow for non-interventional measurement of exposure factors such as operating potential;
- the workload of equipment. This will affect the required frequency of routine testing and maintenance. The frequency of testing should be clearly specified and written in QA schedules. As equipment ages or workload changes, the frequency of testing may need to be adjusted;
- results from commissioning tests (as defined in paragraph 26), which should be used as a baseline when considering the results of future tests. The magnitude of any deviation from the measured baseline value at which remedial action is required (remedial level), or immediate removal from clinical use is required (suspension level) should be clearly specified in QA schedules; and
- the complexity of equipment, which will affect the number of parameters to be measured in a QA programme and hence the time taken for tests to be carried out.

Special consideration should be given to QA programmes for equipment which is used in connection with:

- medical exposures of children;
- a health screening programme; or
- high doses to the patient (such as interventional radiology, computed tomography, nuclear medicine or radiotherapy).

Justification for these examinations or treatments (under IR(ME)R)² is different to those for general medical exposure of adults, as are the consequences of any exposure greater than intended. Considerations

should include the amount, type and frequency of tests included in the QA programme.

Special consideration should also be given to QA programmes for equipment incorporating new or developing technologies (for example computed radiography systems, direct digital radiography systems and intensity modulated radiotherapy systems). In such cases, advice should be sought from the manufacturer and any relevant organisations (such as MHRA, IPEM, BIR or HPA(RPD)) on appropriate parameters to measure, test methods and interpretation of results. Information regarding 'radiation dose issues with digital radiography systems' is provided on the MHRA website at: http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&useSecondary=true&ssDocName=CONO19628. Alternatively you can follow the route from the home page following these links: safety information/general safety information and advice/general and technical information/radiation dose.

It may be useful to see how the requirements of other legislation will be met within the QA programme; such as that relating to mechanical or electrical safety.

28 The QA programme should include written procedures for recording:

- faults on equipment;
- whether the equipment was removed from clinical use;
- what action was necessary to correct the fault; and
- tests made before the equipment was returned to clinical use.

Such fault logs provide an invaluable record of equipment performance and help identify problems that have the potential to cause future exposures much greater than intended (discussed in paragraphs 40-44). Equipment currently unfit for clinical use should be disabled (eg by isolating (and locking off) the unit from the mains supply or, in the case of a mobile unit, removing the main fuse) and posting a notice on the control panel.

29 The QA programme should clearly specify who has responsibility for organising the various elements, carrying out and recording tests or dose assessment, and for acting on adverse findings (such as suspending equipment from use). Results of tests carried out should be properly documented as part of the QA programme.

30 The employer should generally identify suitable test equipment as part of the QA programme, and will need to make arrangements to ensure that this is

provided, maintained and (if relevant) calibrated to an appropriate standard prior to use, and at suitable intervals.

31 Correct calibration of radiotherapy equipment is vital if the prescribed dose is to be delivered to each patient. Advice on calibration of such equipment is given in the Medical and Dental Guidance Notes (MDGN)⁹ and IPEM 81.¹⁰

32 Much equipment used in connection with medical exposures is supplied with programmable electronic control systems, ie computer-based systems which control the operation of the equipment. Hardware failures of such control systems, and/or errors in the software, can cause the equipment to malfunction and may lead to an exposure greater (or less) than intended to ionising radiation. This is a complex area and employers should be aware that the International Electrotechnical Commission (IEC) has produced comprehensive guidance on programmable electronic systems in safety related applications.¹¹ This document is the official IEC statement of safety philosophy for Programmable Electronic system Safety (PES) and where applicable, it will be adopted in the preparation of other IEC standards that have requirements for PES. Typically, this document will be used by industry sectors as the basis of sector-specific and national standards^{9,10,12,13} and HSE will promote the use of the standard in relevant industry sectors and stand-alone applications.

33 General advice is given in L121³ paragraphs 541-549. In addition, detailed information on quality assurance programmes for specific modalities (including criteria of acceptability, remedial and suspension levels and assessment of representative patient doses) are available.^{10, 12, 25}

Maintenance of equipment

34 Equipment used in connection with medical exposure should be under some form of maintenance/service contract, often with the manufacturer or installer. Alternatively, arrangements may be made with in-house engineers and technical staff. In this guidance, all reference to service engineers and service or maintenance includes such in-house arrangements. **In any event, the employer has the legal responsibility for ensuring that equipment is properly maintained and this responsibility cannot be divested to a third party.**

35 It is therefore recommended that employers consult their RPA when the contract is drawn up or reviewed, in order to ensure that the equipment maintenance arrangements are appropriate and assist the employer in meeting their legal duties with regard to IRR99 regulation 32. Appendix 1 details the issues to be considered by employers when arranging for

maintenance of equipment used in connection with medical exposures.

36 The employer should establish clear procedures for acceptance of equipment back into clinical use following service or repair. The procedures may specify the information that will be provided by the engineer (eg test results), together with values of acceptable results of those tests (ie acceptable levels of performance). These procedures might be referenced in the local rules required by IRR99 regulation 17(1). No radiation equipment or ancillary equipment should be accepted back into service until a competent employer representative (such as a senior radiographer or medical physicist) has reviewed the service report/summary to confirm that the equipment has been left in a state fit for use, and that no alterations have been carried out which may significantly affect patient doses or radiation safety. If such alterations have been undertaken, the user should seek advice (for example from the RPA or MPE) before bringing the equipment back into use, as further tests may be needed to verify its performance.

37 Employers should keep adequate records of equipment maintenance. There should be sufficient information recorded to be able to identify, for example, any modification which may affect the patient dose or radiation safety (including software upgrades to electronic control systems). It may be convenient to keep the records of Quality Assurance testing alongside the maintenance record. Records should be maintained for the life of the equipment. When equipment reaches the end of its life the employer must decide whether or not the records should be maintained with respect to the likelihood of liabilities arising from its use. Note that this recommendation is in addition to the requirement for an equipment inventory under IR(ME)R.²

Ageing equipment

38 If equipment has deteriorated in performance since it was installed, to a level which is significantly poorer than any currently acceptable level, it is unlikely to satisfy the requirements of IRR99 regulation 32(1). An example of such deterioration would be if the use of equipment resulted in the doses from medical exposures being significantly greater than local or national diagnostic reference levels (DRLs). The employer should therefore develop a programme for the progressive replacement of equipment before this situation is reached. In determining whether continued use of ageing equipment is justified, and in assigning priorities for equipment replacement, consideration should be given to the following:

- equipment performance (including comparison of recent performance test results with remedial and suspension levels);

- the magnitude of patient doses resulting from the use of that equipment;
- the frequency of use and number of patients likely to be affected by the continued use of the equipment;
- the range of patients likely to be affected by continued use (eg age, clinical condition). Such factors enable a determination of risk versus benefit for continued use of the equipment; and
- the cost of replacement. However, cost cannot normally be used as a legitimate reason for patients being subject to risks in excess of those normally encountered for the examinations undertaken.

The employer should involve the RPA and MPE in the development of equipment replacement programmes.

39 The employer should consider the destination of redundant equipment, eg if the equipment is supplied to a veterinary practice for use in animal radiology, the employer has responsibilities under IRR99 regulation 31. Equipment that is going to be scrapped should be disabled, eg portable dental equipment should have the mains lead removed or circuit boards removed and separated from the generator. Any radioactive sources must be removed from redundant equipment, disposed of via an authorised route and properly accounted for. If it is not reasonably practicable to remove sources from equipment then the equipment itself must be disposed of via an authorised route.

Exposures greater than intended: regulation 32(5), (6) and (7)

Prevention and detection of exposures greater than intended

40 The employer must take all reasonably practicable steps to prevent failure of radiation equipment where such failure could result in exposure of patients to ionising radiation greater than intended. The employer must also implement steps to limit the consequence of such failure (IRR99 regulation 32(5)).

41 Advice on prevention of equipment failure is given in L121³ paragraphs 550-553. If the employer becomes aware of potential defects in equipment during use, they will need to assess, in consultation with the supplier (or the service agent/original manufacturer) and RPA, whether any further action is necessary.

42 If the failure of a single component can give rise to an unintended exposure of the patient, the employer may need to have additional controls in place.^{9,15,21,24} Suitable controls include ensuring that the exposure is automatically terminated within an appropriate preset time, tube current-time product, or dose. Where this is

not reasonably practicable, the employer may need to ensure that failure of equipment to terminate an exposure correctly is immediately detectable, so that the operator can take action.

43 In any case, the employer should have in place mechanisms to quickly detect malfunctions and/or defects in radiation equipment. Special care should be taken in cases where detection of exposures greater than intended is not straightforward; for example in the case of:

- some modern imaging technology (such as computed or direct digital radiography);
- during radiotherapy; or
- the use of radionuclide calibrators for nuclear medicine.

Poor image quality cannot be relied upon to identify malfunctions in diagnostic X-ray or radionuclide imaging equipment. The employer should ensure that checks are made after each radiographic exposure and, in the case of radionuclide dose calibrators, on at least a daily basis prior to administrations of radioactive material, so that exposures greater than intended are prevented or quickly detected.

44 The employer will also need to provide a contingency plan for responding to equipment failures or malfunction. Following equipment failure and subsequent repair, the employer (in consultation with the RPA) should consider the likelihood and consequences of recurrence before returning the equipment to clinical use. Employers should consider the advice given in ICRP 85²¹ and ICRP86.²⁴

Investigation and notification of patient exposures much greater than intended: IRR99 regulation 32(6) and (7)

45 When an employer suspects, or is informed, that an incident may have occurred in which a patient was exposed to ionising radiation to an extent much greater than intended **as a result of malfunction or defect in any radiation equipment**, an immediate investigation must be carried out. Unless the investigation shows beyond reasonable doubt that no such incident has occurred, the employer must immediately notify HSE. This notification should not be delayed pending further investigation. The employer is then required to make or arrange for a detailed investigation of the circumstances of the exposure, and an assessment of the dose received.

46 The employer must keep the initial investigation report for a period of at least two years from the date it was made. If a detailed investigation is made, the report must be kept for a period of at least 50 years from the date it was made (IRR99 regulation 32(7)).

47 Notification is **not** required for increased patient exposures due to ageing equipment whose performance has gradually deteriorated over time, provided the employer is fully aware of this deterioration in performance, and has made a positive decision to continue with its use. Performance specifications (remedial and suspension levels in the QA programme) will have been set for such equipment in consultation with the RPA and MPE. If equipment fails to meet the specification, action should be taken (see paragraphs 26-33). However, if the employer becomes aware of a sudden significant deterioration in the performance of the equipment, and a patient has received an exposure much greater than intended as a consequence, it will be necessary to treat this as an incident subject to notification to HSE under IRR99 regulation 32(7).

48 The requirement to notify HSE is solely in relation to a malfunction or defect in radiation equipment; it does not apply to incidents that occur as a result of errors by those persons performing medical exposures. Incidents caused by human error may need to be notified to the appropriate authority (Department of Health (DH), Scottish Executive Health Department (SEHD), Welsh Assembly Government, or Department of Health Social Services and Public Safety (Northern Ireland) (DHSS&PS) under the requirements of IR(ME)R²)).

49 Sometimes a diagnostic medical exposure is repeated because of failure of ancillary equipment, eg a film processor or gamma camera and associated computer systems. Exposures that in total are higher than normal as a result of such failures are not reportable to HSE under IRR99 regulation 32(7). However, in such cases HSE would expect, as a matter of good practice, the employer to undertake an investigation of the causes and consequences of the incident and implement appropriate measures to limit the likelihood of recurrence. Such incidents may also involve an element of human error, eg failure to recognise that a problem has occurred before a number of repeat exposures have been carried out. In these cases the employer must consider whether notification to the appropriate authority DH under IR(ME)R² is required.

50 MDR⁷ require manufacturers to report to the MHRA, UK competent Authority, any incident which led to, or might have led to, death or serious injury to patients, users and others. HSE therefore recommend users to report any such incidents to manufacturers. In addition, the MHRA, Scottish Healthcare Supplies and DHSS&PS operate a scheme for users to report any adverse incidents concerning medical devices. **The employer is encouraged to report such incidents (even if they have not resulted in patient exposures much greater than intended) as this**

enables the Competent authority (MHRA) to take appropriate actions with the manufacturer.

51 IRR99 regulation 32 defines the requirement for the provision and maintenance of equipment to prevent exposures that are greater than intended. Exposures that are lower than intended can also have serious consequences, especially for therapy procedures (see Appendix 3). An investigation under IRR99 regulation 32(6) is not formally required if the malfunction or defect results in exposures less than intended. However, as a matter of good practice, the employer may wish to carry out their own investigations in such circumstances.

Guidelines on notification

52 If the initial investigation shows beyond reasonable doubt that no incident has occurred or the patient has not received an exposure much greater than intended, the employer should make a simple report of the circumstances that led to the investigation and attach the accompanying evidence. The report is to be kept for two years, IRR99 regulation 32(7).

53 Where the initial investigation indicates that an exposure much greater than intended might have occurred, the employer must notify HSE immediately. Notification should not be delayed pending the outcome of a more detailed investigation. HSE needs to be notified of the basic details of the incident (type of radiation exposure, brief description of events, if possible an estimate of dose received and number of patients affected). The incident should be reported to the local HSE office, the address of which may be obtained from the HSE Infoline on 0845 345 0055 or from the HSE website at www.hse.gov.uk. A fax would suffice. The notification is made under IRR99 regulation 32(6) not RIDDOR.²⁶

54 The employer will need to decide whether or not the patient exposure was much greater than intended. This requires a professional judgement to be made and the employer is advised to consult the RPA and the MPE. However, to assist employers, the guidance in Table 1, Appendix 2 should be used for determining, under most circumstances, when incidents are likely to be notifiable.

55 To use the guidelines in Table 1, Appendix 2, 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.

56 In some cases, the guidelines in Table 1, Appendix 2 will be of limited assistance, for example:

- if the incident involves diagnostic X-ray equipment which does not give post-exposure readout of tube loading factors and does not allow exposure factors to be selected; or
- if the remote after-loading equipment failed to achieve the correct source positioning.

In these cases, it may be difficult to apply the guidelines to a single quantity and thus professional judgement will be particularly important in deciding whether or not to notify HSE of the incident.

57 There may be other incidents involving radiation equipment that the employer ought to investigate, but which fall outside the guidelines for HSE notification. These might include incidents involving a group of individuals, each of whom receives a relatively small additional exposure as a result of an equipment fault.

58 Table 1, Appendix 2 is only relevant to the requirement to notify HSE under IRR99 regulation 32(6); it is not intended to imply that incidents involving a lesser degree of overexposure are in some way acceptable. Regardless of whether or not a particular incident is notifiable, the employer will have responsibilities to minimise the occurrence of such incidents so far as reasonably practicable and to restrict the consequences of patient exposure.

59 The guidelines on notification refer to unintended exposures that may merit an investigation by HSE inspectors. Further explanation of the figures in Table 1 is given in Appendix 2.

60 An unintended exposure of a foetus during a medical exposure is not notifiable to HSE under IRR99, as a foetus is not a person independent of the mother. An accidental exposure of a foetus during a medical exposure is notifiable as part of the mother's exposure, if it results from malfunction of equipment used in connection with medical exposures.

Detailed investigation of incidents

Objectives of investigation

61 There are four main objectives in investigating incidents. These are:

- to establish what happened;
- to identify the defect or malfunction in the radiation equipment and to establish its causes;
- to decide upon and implement remedial action to prevent a recurrence; and
- to estimate the dose received by all persons involved in the incident. Appendix 3 gives advice on assessing patient doses as part of the investigation.

It will probably be useful to analyse the immediate

actions which were taken. The National Patient Safety Agency (NPSA) provides e-based training on root cause analysis, which may prove useful in such investigations, at:
www.npsa.nhs.uk/health/resources/root_cause_analysis.

Persons to involve in the investigation

62 It is important to identify from the outset, or as early as possible, the persons who will be involved in the investigation, including those conducting the investigation and those whose evidence is to be considered. People who should always be involved include:

- the person in charge of the department where the incident took place;
- the person(s) acting as **operator** during the exposure (as defined by IR(ME)R²);
- the service engineer who examined the equipment following the incident;
- the person who was responsible for quality assurance on the equipment;
- the RPA; and
- the RPS.

Others who may be involved include:

- the person acting as **practitioner** for the exposure (as defined by IR(ME)R²) as appropriate;
- the MPE; and
- the patient.

The above list is not exhaustive.

Sources of information

63 Sources of information that may prove helpful both in determination of what happened, and in the assessment of the dose received, include:

- the settings on the equipment, plus any equipment generated logfiles or performance data;
- recorded exposure parameters, such as for diagnostic radiology, including:
 - DAP readings;
 - operating potential (kV);
 - exposure time;
 - Focus skin distance (where available);
 - product of tube current and time;
 and for radiotherapy treatment machine monitor units:
 - beam time;
 - beam modifiers; and
 - geometric settings);
- other measures of exposure (such as for diagnostic radiology: film blackening, image parameters in computed radiography systems (eg CR exposure indicator); for nuclear medicine: count rate in a gamma camera image)). In addition, information may be gained from any

patient TLD measurements undertaken as part of dose assessment programmes;

- QA records (including training records of those persons carrying out QA duties);
- training records of operators to eliminate human error as a major factor (such incidents fall under the requirements of IR(ME)R);²
- any fault reports and service records;
- any tests on equipment carried out for the purpose of the investigation; and
- an account of what happened by the person operating the equipment.

Investigation report

64 It is recommended that the investigation report should include the following:

- the key facts concerning the incident;
- a record of the calculations and measurements that were made; and
- recommendations to avoid recurrence of the incident.

65 The report should be signed and dated by the person who prepared it. It should be copied to the manufacturer or maintenance contractor and retained by the employer for a period of 50 years. It is suggested that a record also be made of the actions taken to implement the report's recommendations. It may also be helpful to include the identity details of the patients involved (name, NHS number, date of birth etc) in the report. It should be noted that any such report should be given appropriate confidentiality, ie marked, stored and distributed accordingly (to comply with the Data Protection Act).

66 Nothing in this publication is intended to indicate whether or not patients should be informed of any incident resulting from malfunction or defect in equipment used in connection with medical exposure and the possible consequences of that exposure. Suitable guidance on this matter may be found in NHS publications: *An organisation with a memory* (2002)²⁷ and *Building a safer NHS for patients* (2001).²⁸

Appendix 1: Maintenance of equipment used in connection with medical exposures

To include any maintenance which may affect the radiation safety of equipment used in connection with medical exposure, or the capability of the equipment to restrict exposure to any person undergoing a medical exposure.

1. The employer and service contractor (or in-house provider) should agree the tests to be undertaken by the contractors and the pass/fail criteria to be applied to these tests. These should be consistent with the remedial and suspension levels chosen by the employer for the equipment. The criteria will depend on one of the following:

- in the case of new equipment, the original specification and/or results of acceptance or commissioning tests. The results of these tests should be used as a baseline with which to compare future performance tests;
- when original records are not available for equipment, tests should be undertaken to establish a baseline performance, the results of these tests can then be used as a basis for future comparisons; or
- for equipment which is no longer able to meet original specification, the minimum acceptable standards may be based on the advice given by the relevant professional organisation or EC criteria.

2. As with frequency of routine tests for the QA schedule, intervals between preventive maintenance inspections should reflect the workload and age of individual items of equipment.

3. Service contractors have an obligation to ensure that any of their employees who undertake maintenance of X-ray equipment are adequately trained and competent to do so (MHRA Device Bulletins DB9801 (Chapter 8)²⁹ and DB2000(02)³⁰). The employer must ensure that any third party service agent can provide the necessary level of expertise. Software diagnostic packages for X-ray generators may need to be licensed.

4. It would be advisable for the service report to refer to agreed tests and the pass/fail criteria applied to the equipment. It is important that any work carried out on the equipment that may significantly affect the patient doses (such as changes to X-ray output or factors relating to image quality) is noted within the report. The criteria should specify what constitutes a significant change in the radiation dose received by patients undergoing medical exposures (and this might be included in the QA programme). The engineer is

advised to highlight in the service report any faults that have not been completely corrected or identified, if those faults could foreseeably lead to a patient exposure that is significantly greater than intended (see paragraphs 40-66). The employer (in consultation with the RPA and where appropriate, mechanical or electrical engineers) should then assess the risk of such occurrence and decide whether bringing the equipment back into service is justified. Following service or maintenance of radiotherapy equipment, the QA tests should identify any changes which might affect patient dose.

Appendix 2

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

Type of diagnostic examination	Guideline multiplying factor applied to intended dose
Interventional radiology, radiographic, and fluoroscopic procedures involving contrast agents, nuclear medicine with intended dose >5mSv and computed tomography examinations.	1.5
Mammography, nuclear medicine with intended $E \leq 5\text{mSv}$ but >0.5mSv, all other radiographic examinations not referred to elsewhere in this table.	10
Radiography of extremities, skull, dentition, shoulder, chest, elbow, knee, and nuclear medicine with intended $E \leq 0.5\text{mSv}$.	20
Type of treatment	Guideline multiplying factor applied to intended dose
Beam therapy, brachytherapy	1.1 (whole course) or 1.2 (any fraction)
Unsealed radionuclide therapy	1.2 (any administration)

Explanation of figures in Table 1

Diagnostic procedures

1. For diagnostic procedures, the guideline factors reflect a level of performance that is significantly outside the normal specification of equipment used for medical exposures.

2. The notification guidelines in Table 1, Appendix 2 are broadly representative of patient exposure, ie effective dose or mean glandular dose. Suitable measurements for determining these quantities are:

- dose-area product;
- duration of exposure;
- product of tube current and time (mAs);
- volume of tissue irradiated; and/or
- activity administered.

3. For diagnostic procedures in nuclear medicine, the radiation equipment likely to be involved in any unintended exposure would be the equipment used to determine the activity of the radiopharmaceutical administered. However, IRR99 regulation 32(6) is not

relevant to equipment which cannot be used directly to control the extent of the exposure, for example if radionuclide calibrators are being used only to provide a rough check on volumetric measurements made for radionuclides, eg ^{51}Cr .

4. The guidelines for nuclear medicine are based on the presumption that the intended dose would be equivalent to the diagnostic reference level of dose (in terms of activity administered for a particular examination determined locally within the national framework provided by Administration of Radioactive Substances Advisory Committee (ARSAC) in their notes for guidance.³¹)

5. The factors in Table 1 are intended to be applied to the entire patient exposure received during the particular procedure in which the faulty radiation equipment was used.

6. HSE should not be notified in cases where equipment failure leads to an exposure which is less than intended and a repeat is carried out, leading to a total exposure for the procedure which is 1.5 times greater than the intended exposure. However, as a matter of good practice, the employer may wish to carry out their own investigations in such circumstances.

Therapeutic procedures

7. In the case of therapeutic procedures (including palliative treatments) for malignant and non-malignant conditions, guidelines are given for a single patient treatment fraction and for a whole course of treatment. The figures of 10% excess exposure for a course of treatment and 20% for a single fraction ensure that the majority of significant incidents would be notifiable. The figures take account of normal clinical tolerance levels of the final delivered dose, and the possibility of unexpected deterministic effects. The figures also reflect a level of performance that is significantly outside the normal specification of equipment used for medical exposure.

8. For radiotherapy and brachytherapy, the guideline factors can be applied to the prescribed dose to the target volume and/or the intended dose to any critical tissues. For therapeutic nuclear medicine, the guideline factor is intended to be applied to the activity of the radionuclide administered to the patient.

General comments on multiplying factors in Table 1

9. The requirement to notify HSE about exposures much greater than intended (IRR99 regulation 32(7)) is to enable HSE to further investigate incidents that may have resulted from a failure to comply with IRR99 regulation 32. The guideline factors are not solely based on increased risk to the individual (a very

complicated determination, which must take into account the range of patient ages, clinical conditions and actual magnitude of the exposure). The single factor of 50% excess (diagnostic) and factors of 10% and 20% (therapeutic) are considered to adequately reflect incidents which may require further investigation by HSE, while retaining a level of simplicity and transparency.

Appendix 3: Assessment of doses to patients following exposures greater than intended

Recommended quantities for assessing dose received

1. An assessment of the dose received, as required by IRR99 regulation 32(6), allows the clinician responsible for the patient to make an assessment of the potential harm caused by the unintended exposure.

Methods for assessing dose

2. In order to provide uniformity in the assessment of doses, possible dosimetric approaches appropriate to seven general categories of procedure are summarised in Table 2. With the exception of radiotherapy and incidents involving only paediatric patients, the methods provide estimates of the effective dose to a **standard** phantom that is representative of an adult patient of average size and composition. It is strongly recommended that the dose assessment be carried out in consultation with the RPA.

3. It is recommended that estimates be made both of the dose actually delivered in the incident and the dose that would have been received if the incident had not occurred. This will allow a comparison to be made. An incident may involve one or more diagnostic or therapeutic exposures.

Table 2 Summary of recommended strategies for dosimetric assessment of incidents arising from different categories of medical exposure

Procedure	Dose quantity ^a	Method ^b
Radiography	E	Estimates of ESD per film or DAP _{rad} and normalised dose data
	D _{max} ^c	Appropriate summation of ESD per film
Mammography	D _{gland}	Estimates of entrance air KERMA per film and normalised dose data
	E ^c	Estimates of doses to other organs
Fluoroscopy & Fluorography	E	Estimates of DAP _{flouro} or entrance surface dose and normalised dose data
	D _{max} ^c	Estimate of entrance surface dose rate and knowledge of procedure used
CT	E	CTDI or DLP and normalised dose data
	D _{max} ^c	Measurements on head or body phantom
Nuclear medicine	E	Administered activity and normalised dose data ⁽³¹⁻³⁴⁾
Paediatrics	E, D _{max} ^c	Use age-specific data when available
Radiotherapy	D _{crit}	Knowledge of dose to radiosensitive organs

Notes

(a) E = effective dose

D_{max} = maximum surface dose

D_{gland} = dose to glandular tissue of the breast

D_{crit} = absorbed doses to the critical organs

(b) ESD = entrance surface dose (with backscatter)

DAP_{rad} = dose-area product for radiographic exposure

DAP_{flouro} = dose-area product for fluoroscopic and/or fluorographic exposure

CTDI = Axial CT dose in free air

DLP = Dose Length Product for a CT examination

(c) These quantities are to be calculated only as necessary when considering the following categories of medical exposure:

D_{max} = radiography, fluoroscopy, paediatrics and CT

E = mammography

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Glossary

		MHRA	Medicines & Healthcare products Regulatory Agency (formed by the merger of the Medical Devices Agency (MDA) and Medicines Control Agency (MCA))
AEC	Automatic Exposure Control		
BNMS	British Nuclear Medicine Society		
DGN	Dental Guidance Notes	MPE	medical physics expert
DHSS&PS(NI)	Department of Health Social Services and Public Safety (Northern Ireland)	NHS	National Health Service
DR	Direct (digital) radiography	NHSBSP	National Health Service Breast Screening Programme
DRL	Diagnostic Reference Level	NIAIC	Northern Ireland Adverse Incident Centre (DHSS&PS(NI))
CR	Computed radiography		
CT	Computed tomography	PACSnet	Picture Archiving and Communication Systems National Evaluation Team
CTDI	Computed tomography dose index	PASA	NHS Purchasing and Supply Agency
DH	Department of Health	PES	Programmable electronic system safety
HPA (RPD)	Health Protection Agency Radiation Protection Division formerly known as National Radiological Protection Board (NRPB)	QA	Quality Assurance
		RCR	Royal College of Radiologists
HSW078	Health & Safety at Work Order 1978 (Northern Ireland)	REMS	Radiation and Environmental Modelling Scotland (formerly NRPB Scotland)
IEC	International Electrotechnical Commission	RPA	radiation protection adviser
ImPACT	Imaging Performance Assessment of CT scanners	RPS	radiation protection supervisor
IPE	Institute of Physics and Engineering in Medicine	SEHD	Scottish Executive Health Department
IR(ME)R	Ionising Radiation (Medical Exposure) Regulations 2000	SHS	Scottish Healthcare Supplies
IRR99	Ionising Radiations Regulations 1999		
KCARE	King's Centre for the Assessment of Radiological Equipment		
L121	Work with ionising radiation. Ionising Radiations Regulations 1999. Approved Code of Practice and guidance L121		
MDGN	Medical and Dental Guidance Notes		
MDR	Medical Devices Regulations 2002		
MEIGaN	Medical Electrical Installation Guidance Notes		

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This document contains notes on good practice which are not compulsory but which you may find helpful in considering what you need to do.

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