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Chapter 3

Radiation protection requirements

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3.1 Introduction

Radiation protection considerations in a radiotherapy department include the following:

- Design of radiation facilities including:
  - a safe design,
  - specification of shielding required,
  - consideration of engineering controls and
  - safety features for routine operation.
- Involvement in the licensing or permitting of the premises.
- Risk assessments of the radiation hazard including those for pregnant staff.
- Development of contingency plans in the event of a radiation emergency.
- Commissioning facilities to confirm the radiation protection requirements are in place and operate correctly. This will include:
  - a critical examination on behalf of the installer and
  - a shielding survey.
- Operational radiation protection during routine operation including involvement in the drafting of local rules and procedures.
- Analysis and advice on any incidents.
- Guidance and assistance with inspections by regulatory authorities.
- Personal monitoring.
- Environmental monitoring.
- Audit of radiation protection arrangements including compliance with conditions of licenses or permits.
- Teaching and training related to radiation protection.
- Consideration of the end of life of the facility, radiation equipment or radioactive source.

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Radiation protection requirements and the complexity of those requirements depend on the type of radiation source, the nature of the hazard and the level of risk as a result of that hazard. If radioactive material is involved, sealed or unsealed, the complexity of radiation protection requirements can increase significantly.

A Radiation Protection Adviser (RPA) as described in the *Ionising Radiation Regulations* 1999 (IRR 1999) should be involved with all the elements above, but the design will have the best outcome if a multidisciplinary team is involved and works cooperatively (see chapter 2). In addition RPAs are involved in a critical examination of the safety features and warning devices in any new installation on behalf of the installer of any equipment; the RPA may be from the installer or the user (IRR 1999, IPEM 2012).

The decisions made as part of the design process are likely to be an integral part of the risk assessments for the facility and should be recorded. A prior risk assessment is also required before work starts with ionising radiation. The design criteria and decisions can be used as part of that assessment.

It should be noted that the greatest risks in radiotherapy in a correctly designed facility are to the patient. Patient safety and treatment accuracy are not part of this report. There are many documents detailing the radiation protection requirements for patient safety and risk assessment (HSE 2000, IRMER 2000, RCR 2008a, RCR 2008b, ICRP 2009).

3.2 Quantities and units

An understanding of the quantities and units used in radiation protection is required to apply the regulations and requirements for facility design and operation. These are outlined below.

3.2.1 Radiation exposure and dose

3.2.1.1 Exposure

The basic quantity that can be measured using an ionisation chamber is exposure with the derived SI unit C kg^{-1}. This is not a particularly helpful unit for radiation protection where the dose to an individual or organ is usually required. The following quantities are all measures of absorption of energy.

3.2.1.2 Air kerma

Environmental dose measurements can be made using suitable conversion factors or calibrations of air kerma (or absorbed dose in air) with the unit of the gray (Gy). This quantity can be calculated and compared with chamber measurements, e.g. during a shielding survey.

3.2.1.3 Absorbed dose in organs

In radiotherapy organ dose is well understood and has the same units as air kerma, i.e. the gray (Gy).

3.2.1.4 Equivalent dose

The quantity air kerma or organ dose multiplied by the radiation weighting factor (table 3.1) is known as the equivalent dose with the units of J kg^{-1}, termed the sievert (Sv). This is the determinant used in this report for the specification of shielding. The radiation weighting factor used to be known as the quality factor. The choice of the correct weighting factor to use for neutron fluences in radiotherapy facilities can be difficult when the energy spectrum of neutrons in a linear accelerator maze and at the maze entrance is uncertain. A factor of 10 is usually used if the energy spectrum is not known. Dose limits for individual organs are set in terms of terms of equivalent dose.

3.2.1.5 Effective dose

The sum of the weighted equivalent doses for individual organs multiplied by the tissue weighting factors (table 3.2) for those organs is the effective dose, again with the unit of the sievert (Sv).

Table 3.1. Radiation weighting factors (ICRP 2007).

Radiation	Weighting factor
X-rays, gamma rays, electrons	1
Protons	2
Neutrons	Continuous function dependent on energy

Table 3.2. Tissue weighting factors (ICRP 2007).

Tissues	Tissue weighting factor
Bone-marrow (red), colon, lung, stomach, breast, remainder tissues	0.12 for each
Gonads	0.08
Bladder, oesophagus, liver, thyroid	0.04 for each
Bone surface, brain, salivary glands, skin	0.01 for each

Effective dose is not a quantity that can be directly measured but is derived from measurements of exposure or air kerma with corrections for the weighting factor of the radiation type and tissue weighting factors when the exposure of an individual is not uniform. Whole-body dose limits and dose constraints for staff and members of the public are set in terms of effective dose.

3.2.2 Operational quantities

Other radiation protection quantities and units are also used, known as operational quantities. These are as follows.

3.2.2.1 Ambient dose equivalent H(d)*

Many dose rate meters, for example, are calibrated to display the ambient dose rate equivalent, which relates to the dose equivalent at a defined depth in the 300 mm tissue equivalent International Commission on Radiation Units and Measurements sphere (ICRP 1996). For most practical purposes in the measurement of gamma rays and x-ray photons this quantity and the air kerma rate are likely to be numerically equivalent.

3.2.2.2 Personal dose equivalent Hp(d)

Personal monitors are calibrated to give the personal dose equivalent from exposure to gamma rays and photons at a prescribed depth of 0.07 mm (Hp(0.07)) or 10 mm (Hp(10)). It should be noted that Hp(10) is indicative of effective dose. For most energies and geometries, Hp(10) is a conservative estimate of effective dose (Zankl 1999).

3.2.3 Dose rate

Measurements and calculations in and around radiotherapy installations are often of dose rate. Dose can be air kerma or ambient dose equivalent as described above. The dose rate can be that at a particular moment in time, i.e. instantaneous dose rate (IDR), or averaged over a period of time. In this case the quantity is known as the time averaged dose rate (TADR), typically over 8 or 2000 h, e.g. $TADR_{2000}$. These quantities and their application in the design of radiotherapy facilities are discussed more fully in section 3.7.

3.3 System of radiation protection

The international system of radiation protection is based on the basic principles of radiation protection laid down by the International Commission of Radiological Protection (ICRP 2007). Justification, optimisation and dose limitation form the basis of all standards and regulatory systems worldwide.

The European Commission (2013) and the International Atomic Energy Agency (IAEA 2014) have both developed a Basic Safety Standard from ICRP statements. The former is a Directive for the basis of radiation legislation in European Union countries and the latter is international guidance for countries without their own legislation in this area. The latest revisions of these documents incorporate annual dose limits for radiation workers and members of the public and a new lower figure for the lens of the eye from the ICRP (2012). New regulations are to be made in the UK in 2018 which are anticipated to include the new limits.

The international system and the Basic Safety Standards have three descriptions for radiation exposure: planned, existing or emergency exposure situations. Radiotherapy is generally a planned exposure situation, although emergency situations also need to be considered. Existing exposure situations may occur in areas of high natural background or if the building material used could cause such a background.

Within each of these situations, there are three categories of exposure: occupational, public and medical. The design of a radiotherapy facility requires consideration of occupational and public exposures. The prescription of medical exposures is outside the scope of this publication but a knowledge of the number of patients, the patient doses and types of exposure is essential for accurate estimation of the radiation workload in the facility (see chapter 4) and to enable a realistic design.

3.4 Regulatory framework in the UK

Regulations in the UK are based on the EC Basic Safety Standard (see above) and each set of regulations has a regulatory authority and a local expert adviser who may have to hold a certificate of competence. These are set out in table 3.3.

The IRR (1999) are designed to protect staff and the public from exposure to ionising radiation arising from work with radiation. They do not apply exclusively to work in the medical sector, although there are some regulations applying to equipment used for medical exposures.

The *Ionising Radiation (Medical Exposure) Regulations* (IRMER 2000) are designed to ensure that the patient receives the prescribed dose from ionising radiation.

The *Environmental Permitting Regulations* (EPR 2016) supersede and combine a number of amendments made since these regulations were implemented in 2010 (EPR 2010). These are designed to protect the environment from the impact of the use of radioactive material. There is some overlap with the IRR in terms of source control and regulatory requirements for the management of sources. These incorporate the requirements originally laid down in the *High Activity Sealed Source Regulations* (HASS 2005), which relate to high activity sealed sources and apply in many radiotherapy centres with high dose rate (HDR) brachytherapy.

The *Carriage of Dangerous Goods and Transportable Pressure Equipment Regulations* (HSE 2009) and subsequent amendments cover the transport of radioactive material by road, rail, sea and air. They reflect the requirements of the ADR

Table 3.3. Statutory regulations impacting on radiotherapy.

Regulation	Regulatory authority	Expert adviser
IRR99	HSE	RPA
IR(ME)R2000	DH/CQC	MPE
RSA/EPR	Environment Agencies	RWA/CTSA
Transport	ONR	RPA/DGSA
REPPIR	HSE	RPA
MARS	DH/ARSAC/CQC	MPE

Key: RPA—Radiation Protection Adviser; MPE—Medical Physics Expert; RWA—Radioactive Waste Adviser; DGSA—Dangerous Goods Safety Adviser; CTSA—Counter Terrorism Security Adviser; HSE-Health and Safety Executive; DH-Department of Health; CQC-Care Quality Commission; ONR-Office of Nuclear Regulation; ARSAC-Administration of Radioactive Substances Advisory Committee

(*Accord Europeen relative au transport international des marchandises dangereuses par route*) (UNECE 2017) which are updated every two years.

The *Radiation (Emergency) Preparedness and Public Information Regulations* (REPPIR 2001) relate to the emergency arrangements in the event of incidents involving large amounts of radioactive material. Emergency plans required under these regulations are not generally required by hospitals.

The *Medicines (Administration of Radioactive Substances) Regulations* (MARS 1978) relate to the administration of radioactive material to humans. They apply to oncologists practising brachytherapy but will not be discussed further here.

It is necessary to consult an RPA on a range of matters under the regulations listed above and the appointment of an RPA is required in centres carrying out radiotherapy. They are required to have suitable and sufficient knowledge of radiotherapy facilities and practice to be able to advise appropriately. A certificate of competence from RPA2000 is a recognition of competence but not necessarily suitability. Medical RPAs are expert in the regulations but perhaps not always in the practice of radiotherapy.

Medical Physics Experts (MPEs) are required to be appointed in radiotherapy. They are likely to be an integral part of the radiotherapy department and have expert knowledge of radiation dosimetry and clinical radiotherapy practice. Certification of these experts is expected to be required following new regulations in 2018.

A Radioactive Waste Adviser (RWA) to advise on radioactive waste and other radiation protection matters is required to be appointed by an employer holding permits under the Environmental Permitting Regulations (EPR 2016). A certificate of competence under RPA2000 is a recognition of competence but employers are required to ensure the RWA has suitable experience to give advice on the employer's specific practice.

A Dangerous Goods Safety Adviser is required under the Carriage of Dangerous Goods Regulations (HSE 2009) when transporting radioactive material. Many centres employ transport companies to transport radioactive material if needed, although a derogation currently exists to allow professionals to transport material without the external warning signs in private cars provided suitable insurance is in place and a range of other conditions are met. Some UK insurance companies will not cover this activity.

The employer is ultimately responsible for ensuring that all regulations are complied with. A Chief Executive Officer (CEO) of an organisation is unlikely to be able to directly implement the requirements and it is normal for them to delegate tasks to others in the organisation through the management chain. These persons in turn need to feedback through that chain to assure the CEO that the regulations are being implemented satisfactorily. When the experts are also employees, there may need to be careful division between roles when expert advice is being given and when the employer has delegated tasks to the expert to complete on their behalf to meet the requirements of the regulations.

Other roles on a more operational level include the Radiation Protection Supervisor (responsible for ensuring radiation protection policy and procedures are being followed in their area of responsibility), those supervising the use of sealed

radioactive sources (sometimes called 'source custodians'), those supervising the use and disposal of unsealed radioactive material, and managers in individual areas.

Following the publication of the new EC Basic Safety Standard Directive (European Commission 2013) in 2013, the UK regulators have reviewed IRR99, IRMER2000, and the REPPIR and MARS regulations. These reviews will result in new regulations to be enacted in 2017 and 2018. It is expected that there will be some additional requirements for radiotherapy centres to address. These are expected to include some form of registration under the new IRR and changes relating to the use of radioactive material in radiotherapy treatment.

3.5 Basic radiation protection principles in radiotherapy

3.5.1 Justification

All radiation exposures are required to be justified. Justification of staff and public exposure resulting from radiotherapy is covered by the EC Basic Safety Standard (European Commission 1996) and includes a requirement for some form of registration of the facility. IRR (1999) contains a generic authorisation covering the use of electrical equipment to produce x-rays for the purpose of the exposure of persons for medical treatment, i.e. linear accelerators or kilovoltage units in radiotherapy. This situation is expected to change when the new regulations are made in 2017/18 and registration under the new regulations is likely to be required. Currently there is a requirement to notify the regulatory authority (the Health and Safety Executive in the UK) when working with ionising radiation for the first time or when changing the use of the facility, e.g. adding the use of radioactive material. Any notifications made under IRR (1999) will not be valid under the new regulations and a new notification or registration as described above will need to be made.

When radioactive material is used, the UK has had a system of licensing premises since 1993 under the Radioactive Substances Act (RSA 1993). This has been superseded in England and Wales by the Environmental Permitting Regulations (EPR 2016).

If permits are required, early engagement with the regulators/licensing authorities is recommended. There are often conditions associated with licenses which may affect the design of the facility, e.g. the standards of doors for security purposes. Some requirements may also affect the basic layout of the facility.

3.5.2 Optimisation

Optimisation in terms of radiation protection is realised by keeping doses as low as reasonably achievable (ALARA). For radiotherapy installations, this is achieved by setting dose constraints at the planning stage to calculate the level of shielding required and the specification of appropriate engineering controls for an installation both in terms of operational capability and location. As there are few occasions when workers remain with a patient during treatment, optimisation of staff protection is largely performed at the design stage of the facility.

3.5.3 Dose limitation

The system of dose limitation has remained unchanged since the levels set by ICRP Report 60 in 1991 (ICRP 1991) apart from the dose limit for the lens of the eye which has been reduced in ICRP Report 118 (ICRP 2012). There are dose limits for workers, the public and young people, but not for patients undergoing medical exposures. These are listed in table 3.4. Classification is required when 3/10 of a dose limit may be reached. Classification of workers in radiotherapy is now relatively rare as whole-body doses are unlikely to reach even the dose limits for members of the public. The reduced limit for the lens of the eye means that classification will be required if 15 mSv is likely to be exceeded. It is not anticipated that this dose could be exceeded in radiotherapy in current routine circumstances.

3.6 Controlled areas

Areas in radiotherapy where radiation treatment is carried out are always designated as controlled areas. A controlled area is defined as one where special measures are needed to restrict exposure in either a planned or emergency exposure situation.

It is common to define the controlled area as the room, i.e. the boundaries are specified by the walls, floor, ceiling and doors. There may be some points within this area where special measures are not required, but for simplicity of physical definition, description and access control the physical boundaries are used. Areas outside treatment rooms are not normally controlled areas, although the roofs of linear accelerators can be an exception during operation, when access needs to be controlled. Treatment rooms may not be treated as controlled areas when the equipment is not powered to provide radiation beams. Installation of new equipment into existing facilities will require new risk assessments in the areas outside treatment rooms. Some centres designate controlled areas outside treatment rooms on the basis of dose rates and or anticipated doses per annum from the use of the equipment.

Table 3.4. Dose limits in 2016, anticipated new eye dose limit for employees in brackets (IRR 1999, European Commission 2013).

Annual dose limits (mSv)			
Site	Employees	Trainees (under 18)	Others
Whole body	20	5	1
Lens of eye	150 (20)	50	15
Skin (1 cm^2)	500	150	50

Other limits

Abdomen of women of reproductive capacity 13 mSv in 3 months.
Other persons exposed as a result of someone else's medical exposure (but not a comforter and carer) 5 mSv in 5 years.

When an assessment is made that an area need not be designated as a controlled area but that the situation needs to be kept under review, then the area concerned should be designated a supervised area. Signs and demarcation are not required for these areas but they should be identified as such in the Local Rules. Supervised areas are the exception in radiotherapy.

3.7 Optimisation in the design process

Some basic assumptions are made to enable the shielding to be calculated. Radiation workload is covered in individual chapters but the principles below are applied in all modalities.

3.7.1 The radiation protection working year

As radiotherapy equipment is increasingly operated over extended working days, up to seven days a week, it is important that shielding is not over specified as a result. It is recommended that no matter what the working pattern of the equipment is, it is the work pattern of staff (and the associated equipment use during that time) that should be considered. Usually this is based on eight hour shifts, a five day working week and a working year of 50 weeks. On this basis 2000 hours per year is the accepted conservative figure for the work pattern. Under exceptional circumstance, e.g. in the case of residential property adjacent to the facility, consideration of the total dose during the entire operation of the facility should be considered.

3.7.2 Occupancy factors

The occupancy factor is the time spent by critical groups of people at the location in question. Factors in the report *Radiation Shielding for Diagnostic Radiology* (Sutton *et al* 2012a) are shown in table 3.5 and the factors in NCRP Report 151 (NCRP 2005) in table 3.6.

The appropriate value of the occupancy factor can be contentious. For control areas and offices a factor of 100% should be used. For a neighbouring linear accelerator bunker 50% is reasonably conservative for positions 300 mm from the wall of that bunker. A higher figure might be used in the centre of the room where staff might spend more time.

Ranges are suggested in table 3.5 so that the local situation can be reflected against the knowledge of factors generally used elsewhere. This can be particularly applicable to corridors, some of which are heavily used and others rarely. Values outside the suggested ranges can of course be used. UK values tend to be higher than US values (table 3.6). A reasonable compromise is 10% for corridors, 50% for staff rooms, 20% for the entrance to the maze, 10% for patient waiting areas and 5% for car parks. When assigning a low occupancy factor it is important to consider where the persons concerned might be for the rest of the time.

Where low occupancy values have been assumed it is important that this is clearly documented so that if the use of the area changes an appropriate reassessment can be made. The report *Radiation Shielding for Diagnostic Radiology* (Sutton *et al* 2012a) recommends that occupancy should never be less than 5%. Use of a lower occupancy

Table 3.5. Occupancy factors from the report *Radiation Shielding for Diagnostic Radiology* (Sutton *et al* 2012a).

Occupancy factors provided for general guidance	
Occupancy and location	Suggested range (%)
Full occupancy	100
Control rooms	
Reception areas, nurses' stations	
Offices, shops, living quarters, children's indoor play areas, occupied space in nearby buildings	
Partial occupancy	2–50
Staff rooms	
Adjacent wards, clinic rooms	
Reporting areas	
Occasional occupancy	5–12.5
Corridors	
Store rooms, stairways	
Changing rooms, unattended car parks	
Unattended waiting rooms	
Toilets, bathrooms	

Table 3.6. Suggested occupancy factors from NCRP Report 151 (NCRP 2005).

Location	Occupancy factor
Full occupancy areas (areas occupied full-time by an individual), e.g. administrative or clerical offices, treatment planning areas, treatment control rooms, nurse stations, receptionist areas, attended waiting rooms, occupied space in nearby building	1
Adjacent treatment room, patient examination room, adjacent to shielded bunker	0.5
Corridors, employee lounges, staff rest rooms	0.2
Treatment room doors	0.125
Public toilets, unattended vending rooms, storage areas, outdoor areas with seating, unattended waiting rooms, patient holding areas, attics, janitor's closets	0.05
Outdoor areas with only transient or vehicular traffic, unattended parking lots, vehicular drop off areas (unattended), stairways, unattended elevators	0.025

with an annual dose constraint of 0.3 mSv implies that the area concerned could have an exposure greater than 6 mSv per year and should be a controlled area.

Care is needed if shielding is sited close to a party boundary. The use of the adjacent land may change, which may affect the design assumptions used, particularly if an occupancy factor has been applied.

3.7.3 Annual dose constraints

IRR99 Regulation 8 (IRR 1999) describes many ways in which exposures should be restricted and doses kept to levels as low as reasonably achievable, i.e. optimisation of exposure. The use of dose constraints when planning facilities can be used to meet this requirement. The Approved Code of Practice to IRR99 (HSE 2000) describes the use of a constraint for members of the public from a single source to be a maximum of 0.3 mSv per annum. This figure is the accepted value for the design of linear accelerator bunkers in the UK[1]. The same constraint of 0.3 mSv per annum can be recommended for members of staff, but it is acceptable to design to a higher constraint. 1 mSv per annum is often chosen if 0.3 mSv per annum is not deemed appropriate.

3.7.4 Time averaged dose rate

The TADR over 2000 h for an annual dose constraint of 0.3 or 1 mSv per annum is 0.15 or 0.5 μSv h^{-1}, respectively. This would be the dose rate if the exposure was continuous throughout that period. The occupancy and orientation factors (see chapter 4) should both be applied to calculate the TADR.

3.7.5 Instantaneous dose rate

Equivalent dose rate (taking account of the radiation weighting factor) has been used to decide on the designation of areas, as described in section 3.6 above. Whilst there are circumstances where the IDR must be noted, a value of 7.5 μSv h^{-1} is too restrictive for the routine clinical use of most radiotherapy equipment. The transitory nature of the dose rate at a point from a linear accelerator, primarily due to the movement of the gantry and from the modulation of a small beam, results in a person outside the bunker being exposed to the beam for only a few seconds. This supports the approach that it is more appropriate to use the annual dose constraint as the limiting factor for shielding design for this type of equipment, even in high dose rate (flattening-filter-free (FFF)) mode (see chapter 4). It is recommended that shielding calculations are carried out with the aim of achieving the annual dose constraint and that the IDRs are reviewed to ensure they are not too high. These reviews can indicate numerical values of some tens of μSv h^{-1} and are considered acceptable under current operational circumstances for FFF linear accelerators. Some RPAs experienced in bunker design will accept up to 100 μSv h^{-1}. It is important that the RPA understands how the equipment will be used, any weaknesses in shielding such as penetrations through barriers, and the critical points outside the bunker to enable appropriate advice to be offered.

Restricting this value to, for example, 7.5 μSv h^{-1} will lead to more shielding being installed than is required. Controlled areas are defined in IRR99 Regulation 16(1) (IRR 1999) as being areas where special procedures are required to restrict significant exposure to an individual in that area or to limit the probability of a

[1] In the USA a shielding design goal of 1 mSv per year is advocated for uncontrolled areas (NCRP 2005).

radiation accident and to limit its magnitude, or if it is likely that an individual in that area would receive an effective dose in excess of 6 mSv per year or three-tenths of any other dose limit for a radiation worker aged 18 years or over. Provided the dose in areas outside the bunker meet the constraint then there is no need to designate areas as controlled under the regulations. This aspect should be kept under review in risk assessments to ensure that the basis for the original design is still relevant.

This is in line with the views expressed in the British Institute of Radiology (BIR) report *Radiation Shielding for Diagnostic Radiology* (Sutton *et al* 2012a) which uses only a design constraint of 0.3 mSv per year (3/10 of 1 mSv per year), with no reference to TADRs over a minute. This view has been further clarified in a letter in the *Journal of Radiological Protection* (Sutton *et al* 2012b) that states that the 0.3 mSv per year constraint should be adhered to but that a 7.5 μSv h^{-1} IDR averaged over a minute constraint is not considered valid for diagnostic radiology. It is the view of the authors that using this constraint in shielding calculations for linear accelerator bunkers using FFF beams is also neither valid nor appropriate.

3.7.6 Other dose constraints/time averaging

It might be appropriate in some circumstances to apply a dose constraint over a shorter period to ensure doses are as low as reasonably achievable. A weekly dose or daily dose might be reasonable for some circumstances; for example if patterns of treatment were not constant. The dose constraint should not be lower than 1/50 of the annual dose constraint for a weekly constraint or 1/250 for a daily constraint, but could be much higher to take account of the distribution of radiation exposures over time.

The recommendations of this section are summarised in table 3.7.

3.8 Engineering controls

A hierarchy of control measures are used to restrict exposure of persons. Shielding is foremost, but medical applications require access to treatment rooms, so it is expected that there will be interlocks, warning devices and safety features built in

Table 3.7. Parameters used for optimising exposure in the design process.

Parameter	Recommended values
A year	2000 h
Annual dose constraint	Maximum of 0.3 to 1 mSv
IDR	No numerical limit provided the annual constraint is met.[a]
Other dose constraints	Weekly greater than or equal to 1/50 of the annual dose constraint. Daily greater than or equal to 1/250 of the annual dose constraint.[b]
TADR2000	<0.15–0.5 μSv h^{-1}
Occupancy factors	See table 3.5

[a] Provided the use of the equipment is well understood and applied in the design as described in section 3.7.
[b] Could be much higher than the fraction quoted.

at the design stage. Only then should written systems of work be used to restrict exposure.

Interlocks are generally required at the entrance to radiotherapy treatment rooms. These may be incorporated into a door closing mechanism, a physical barrier or a light curtain at the maze entrance. The interlock terminates the radiation beam if the door or barrier is opened or the light path is broken. The interlock circuitry should require the treatment unit to be reset before the radiation exposure continues; the exposure should not continue if a door or barrier is simply closed.

A 'last person out' (LPO) button is generally incorporated within the treatment room. Its position is sited such that the whole room should be visible from its position. Whilst industrial practice is to sweep an area and place the LPO button in the far side of a room, this could be disconcerting for the patient. The local risk assessment will consider the location of the button. Common practice is for it to be sited close to the inner maze entrance but where the operator has clear sight of the whole room. Some installations may have areas which are not visible, e.g. areas behind linear accelerators or room furniture. The latter is not desirable and may therefore require an audible warning of imminent radiation exposure to be installed. This again is disconcerting for the patient who may already be anxious. Interlocked doors are recommended for equipment areas behind linear accelerators which are incorporated into a fascia. If a light curtain is used a final closure of the interlock should be made with a second button outside the room to confirm no one other than the patient is inside.

There should be a visible indication of radiation present in the treatment room such as a red panel light indicating its presence, visible to anyone in the room or the maze.

Warning lights are normally fitted at the entrance to the controlled area to cover the regulatory requirement to demarcate the controlled area. These are ideally positioned at eye level either side of the entrance to the treatment room, but the design of many entrances means the exact positioning is sometimes above or to one side of the entrance. The wording needs to include a description of the hazard which may include x-rays, electrons and neutrons. Care is needed in the specification of any legend. A two stage warning light is commonly used (see figure 7.16). The upper yellow section is illuminated when the equipment is powered and can provide radiation. The red section is illuminated when radiation is being generated. Some centres use a three stage warning light with one section confirming to those outside the bunker when the LPO circuit has been closed.

When a radioactive source is part of the equipment, an independent radiation monitor to measure the presence of ionising radiation should also be installed in the treatment room with an audible indication of dose rate to indicate whether or not the source has returned to the safe position after treatment.

The equipment itself contains many engineering controls, fail safe devices and warning devices to restrict exposure and to fail safely should fault conditions develop. International standards exist for the specification of these (IEC 2009) and their operation should be understood, in particular by those carrying out the critical examination of the installation so that their operation can be checked.

Wherever there are engineering controls, their operation should be checked regularly to ensure they are operating correctly. The frequency of those checks will be decided as part of the risk assessment and will depend on their criticality and their potential for failure. Some will be checks before use or daily, others will be less frequent. They will be incorporated into the quality assurance regime for the equipment concerned (e.g. *Technical Quality Control Guidelines* of the Canadian Partnership for Quality Radiotherapy (CPQR 2016)).

3.9 Prior risk assessment

An assessment is required of the risk to employees and members of the public from the use of the ionising radiation. This is required to identify the measures required to restrict the exposure of those persons to the radiation. Consideration must also be made of any potential accidents and the nature and magnitude of any potential exposure. There are many sources providing advice on risk assessment, for example on the Health and Safety Executive website (www.hse.gov.uk/risk) or in the Medical and Dental Guidance Notes (IPEM 2002). All findings from the assessment should be recorded.

The assessment should include the following:

- The nature of the sources, e.g. x-rays, electrons, sealed sources, other radiation (e.g. neutrons), or unsealed material including radon gas. This shows the type of hazard—external dose, internal radiation or contamination.
- The likely doses that individuals might receive in normal circumstances and in potential accidents. It is common for separate assessments to be completed during commissioning and in routine clinical use. The design criteria for the installation can be used for this assessment and consideration of where individuals might be in the event of an incident, e.g. accidental exposure to the source or a requirement to enter the treatment room during an exposure. Consideration needs to be given to possible exposure in the event of failure of any of the engineering controls and design features planned for the installation.
- The results of the shielding survey will almost always form part of the assessment. Long term assessment of doses around the site is often carried out but the siting of dosimeters, but their lack of sensitivity may limit the actual value of such measurements. If the room was used for a similar purpose previously, previous monitoring results may help in this assessment. These can be updated with data from the actual facility once results are available.
- Additional consideration is required for equipment using radioactive material where potential exposures and accidents will need considering and also whether contamination needs to be considered and what levels might be encountered. Consideration is also required of source movement, loss and theft.
- Safe systems of work. These should be considered as part of the design stage and are likely to include a requirement for persons to be outside the controlled area during any exposure.

The outcome of the assessment will result in the following:

- Confirmation that the dose constraints will be met.
- Specification of the shielding required.
- The engineering controls required such as interlocks, etc.
- Local rules including systems of work.
- The contingency plans required.
- The requirements for personal dose monitoring.
- Designation of controlled areas.
- The methods required to restrict access to controlled areas.
- The training needs of staff who need access to controlled areas.
  Consideration needs to be given to all groups of staff who may need to gain access including cleaners and hospital maintenance staff.
- Any restrictions for pregnant staff so that the foetus is not exposed to significant levels.
- If unsealed radionuclides are used, the restrictions (if any) for breast feeding staff so that the child is not exposed to significant levels.

The risk assessment can also be used to record the requirements for decommissioning of the facility. All these findings may impact on the content of the local rules. An example for a linear accelerator is given in figure 3.1 and an example for HDR brachytherapy in figure 3.2.

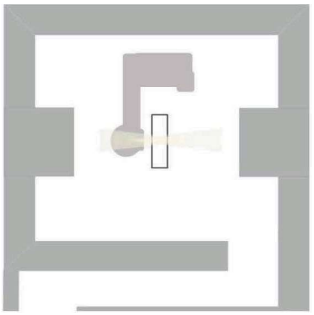
The local rules may be different during the installation and commissioning phases of new equipment. The controlled area is generally under the control of the equipment manufacturer or supplier during the installation phase. This is often handed over to the user after joint acceptance testing, which will include the critical examination, has been completed. Access arrangements and modes of operation may differ from normal clinical operation during these phases and particular care is required to ensure all hazards have been considered and the risks minimised.

3.10 Additional regulatory requirements

A number of other requirements are identified in the regulations. These are applicable to radiotherapy and other areas. Specific additional requirements are described in individual chapters.

3.10.1 Investigation level and personal dose monitoring

Doses received by employees and members of the public will be much lower than the dose limit. An investigation level is set as an aid to optimisation to demonstrate doses are as low as reasonably achievable. For staff who are unlikely to get significant doses these can be set quite low. The doses recorded on personal dosimeters can also be used to carry out investigations of unexpected high readings. It should be noted that personal doses in radiotherapy can be very low. In some centres staff are not monitored routinely. In others the dosimeter results are used to

RISK ASSESSMENT	Hospital Anytown Room LA1 Date 2014
Radiation equipment/sources involved	Linear accelerator make/model/serial no. Room is a purpose built bunker on the ground floor designed for 15 MV and 10 MV x-rays. Adjacent to staff room on one side. All other sides—low occupancy. Two walls external walls—car park and roadway. No routine access required to area above bunker.
Clinical procedures & anticipated workload	Radiotherapy treatments are standard isocentric treatments with *x* MV x-rays, *y* patients per day and *z* Gy per patient.
Staff involved	Radiographers, physicists, engineers, porters, other maintenance staff.
Other persons involved	Patients being treated. Visitors.
Exposed groups & dose constraints	Members of the public 0.3 mSv. Staff *x* mSv whole body (and fingers if appropriate). Pregnant staff 1 mSv to abdomen (consider emergency situation). Comforters and carers 5 mSv.
Diagram 	Room layout. Surrounding areas occupancy (including above and below). Monitoring devices location. Warning lights location. Engineering controls location, especially emergency off position. LPO button, other interlocks. Operator(s) positions(s). Equipment/source location.
Potential emergency situations	Fire. Medical emergency. Security. Damage.
Assessment of likely doses: routine operation	Average body doses for 2013 were less than 0.1 mSv in 3 months for radiographers, physicists and engineers.

Emergency situations	In an emergency situation dose limits could be approached in a few seconds.
Control measures	Shielding. LPO button. In-room monitor/light. Door interlock. Operation of equipment. Emergency off switches. Records. Engineering controls. Other warning devices. Monitoring arrangements. Access restrictions to roof.
Action to be taken	Training-equipment and radiation protection. Local rules. Checking of interlocks and warning devices. Review monitoring results. Contingency plan.

Signature _____ **Date**_____

Title _____

Review date_____

Figure 3.1 Sample risk assessment for a linear accelerator in standard operation.

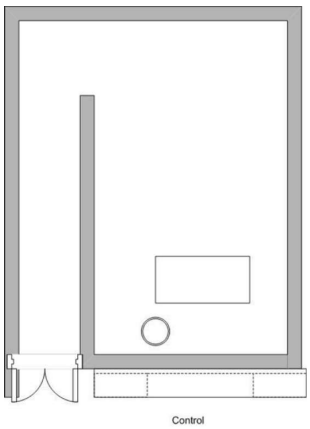
confirm that environmental doses are not approaching levels of concern and to reassure staff.

3.10.2 Critical examination

The installer of equipment producing radiation, including medical equipment such as linear accelerators and CT scanners, is responsible for ensuring a critical examination of the equipment is carried out under IRR99 Regulation 31 (IRR 1999). An RPA is required to be involved in the UK, although not necessarily present during this examination. IPEM has published guidance on critical examinations in diagnostic radiology (IPEM 2012). An example of the points that might be covered in a critical examination in radiotherapy is set out in table 3.8. If the installer of the equipment is not responsible for the bunker design or is installing into an existing bunker, they cannot be responsible for the shielding or its integrity.

3.10.3 Warning signs

Radiation installations must have warning signs to demarcate the controlled area (IRR 1999). Their format is documented in the Medical and Dental Guidance Notes

RISK ASSESSMENT	Hospital Anytown Room HDR Date 2016
Radiation equipment/sources involved	Afterloader make/model/serial no. Activity and radionuclide. Room details. External occupancy.
Clinical procedures & anticipated workload	Brachytherapy treatment procedures. Patients/procedure. Dose/procedure.
Staff involved	Doctors, nurses, radiographers, physicists, engineers, porters, other maintenance staff.
Other persons involved	Patient being treated.
Hazards	External irradiation. Loss or damage to the source.
Exposed groups & dose constraints	Members of the public 0.3 mSv. Staff *x* mSv whole body (and fingers if appropriate). Pregnant staff 1 mSv to abdomen (consider emergency situation). (Comforters and carers 5 mSv.)
	Room size/door/protective screens. Surrounding areas occupancy (including above and below). Monitoring devices location. Warning lights/sign location. Engineering controls location (if applicable). Patient orientation. Operator(s) positions(s). Distance to source. Equipment/source location. Lead pot, etc.
Potential emergency situations	Fire. Medical emergency. Security. Damage. Source stick.
Assessment of likely doses: Routine operation	<0.3 mSv routine operation.
Emergency situations	In an emergency situation dose limits to fingers could be approached in a few seconds.

Control measures	Shielding/protective screens. Handling of radioactive sources/operation of equipment. Records. Engineering controls especially emergency off switches. Warning devices. Personal protective equipment (PPE). Monitoring arrangements. Measures to minimise spread of contamination. Access arrangements.
Action to be taken	Training-equipment and radiation protection. Local rules. Checking of interlocks and warning devices. Review monitoring results. Contingency plan rehearsals.

Signature _____ **Date**_____

Title _____

Review date_____

Figure 3.2. Sample risk assessment for HDR brachytherapy.

(IPEM 2002) and is enshrined in law in the Safety Signs Regulations (Safety Signs 1996). These are normally supplemented by warning lights (see section 3.8 above).

3.10.4 Quality assurance and maintenance

The life cycle of equipment is well documented with requirements for quality assurance, quality control checks and maintenance. This is particularly important for radiotherapy to ensure the correct dose is delivered to the planned location. Regular maintenance should be undertaken according to the equipment manufacturer's recommendations. Guidance about equipment, its life cycle and action to be taken when there is an equipment failure is the subject of specific guidance in PM77 (HSE 2006). Regular quality control checks are required and professional guidance is available (e.g. CPQR 2016).

Equipment handover before and after maintenance is of particular importance in radiotherapy and the availability/non-availability of equipment for clinical use should be clearly indicated at the control desk. Some centres keep a signed record of handovers. This forms part of the quality system (quality assurance in radiotherapy (QART)) within the radiotherapy department.

3.10.5 Incidents

Radiation incidents involving equipment failure in radiotherapy are rare. Because of the potentially fatal consequences in the event of equipment failure, equipment is

Table 3.8. Points to be considered in the critical examination of a linear accelerator.

Parameter
Room warning signs
Room warning lights: ready to emit radiation.
Room warning lights: 'do not enter'.
Audible exposure warning.
Visible exposure warning in maze.
Warning signals:
Mains on.
Exposure warning lights/indicators on the control panel.
Room protection:
General adequacy of protection.
Adequate shielding of walls and doors.
Surrounding dose rates meet design specification.
Engineering controls
LPO button.
Maze barrier interlock.
Emergency off buttons.
Labelling
Controlled area.
All controls clearly labelled.
Model and serial number.
CE mark.

carefully designed with fail safe mechanisms central to all control systems. There are also back-up systems which can be multi-layered. Changes to operational software, however, add a new vulnerability and upgrades must be subject to careful checks before patient exposure.

In the UK, notification to regulatory authorities is required when a dose much greater than intended is given to a patient (10% for a course of treatment or 20% for an individual fraction in radiotherapy) as defined in PM77 (HSE 2006). However, such notifications due to equipment failure are rare. Incidents involving a break-down in procedures or human error are more likely, but are outside the scope of this report.

3.10.6 Contingency plans

Contingency plans are required to be developed to consider all the relatively foreseeable events around the use of radiotherapy equipment such as fire, theft, equipment failure or a medical emergency. These should examine the risks to both staff and patients.

A contingency plan for a linear accelerator might be relatively simple and involve turning the unit off.

However, for HDR brachytherapy, the contingency plan needs to consider a range of scenarios. The most critical is the radiation source becoming stuck outside the safe, resulting in unintended doses to the patient and staff. The plan must be rehearsed at regular intervals and with new staff so that all the necessary processes are second nature to the staff operating the unit.

References

CPQR (Canadian Partnership for Quality Radiotherapy) 2016 *Technical Quality Control Guidelines* www.cpqr.ca/programs/technical-quality-control/ (Accessed: 10 October 2016)

EPR 2010 *The Environmental Permitting (England and Wales) Regulations* SI 2010/675 (London: The Stationery Office)

EPR 2016 *The Environmental Permitting (England and Wales) Regulations* SI 2016/1154 (London: The Stationery Office)

European Commission 2013 Laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation *Council Directive* 2013/59/Euratom (Brussels: European Commission)

European Commission 1996 Laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation *Council Directive* 96/29/Euratom (Brussels: European Commission)

HASS 2005 *High Activity Sealed Source Regulations* SI 2005/2686 (London: The Stationery Office)

HSE (Health and Safety Executive) 2000 *Work with Ionising Radiation: Approved Code of Practice and Practical Guidance on the Ionising Radiations Regulations 1999* L121 (London: HSE)

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