

“RADIATION SAFETY POLICY”

The following is chapter 12 of the Hull & East Yorkshire Hospitals' *Health & Safety at Work Policy* (CP137, issued 4/12/09).

Minor corrections or changes not included in this current version of CP137 but proposed by the RPA for the next version are shown in **red**.

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12. Policy on the Use of Ionising & Non-Ionising Radiations

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12.1 INTRODUCTION, POLICY STATEMENT & SCOPE

Particular hazards arise from the medical use of IONISING & NON-IONISING RADIATIONS. Various pieces of legislation address these hazards, enforced by several different government agencies.

This policy aims to ensure that the Trust remains compliant with all radiation legislation, and that the risks to persons arising from the use of IONISING & NON-IONISING RADIATIONS by the Trust are as low as reasonably practicable consistent with the health benefits intended.

The following uses of IONISING & NON-IONISING RADIATIONS are addressed by this section of the Health & Safety Policy

IONISING RADIATIONS

- All uses of X-rays
- All uses of radioactive substances, except for smoke detectors
- All uses of electron, neutron, beta particles, alpha particles, positrons and all other ionising radiations
- Radon in the workplace

NON-IONISING RADIATIONS

- Class 3B or class 4 laser products and intense pulse light sources ("IPL")
- Therapeutic use of ultraviolet light
- Magnetic resonance imaging

Many of the principles and sources of information outlined in this policy may also be of use for other radiations introduced into the healthcare environment.

An up-to-date list of legislation, guidance and codes of practice is maintained on the Trust's Radiation Physics website at www.hey.nhs.uk/hullrad/legislation.asp . Most of these documents can be downloaded via this website.

No new source of ionising radiation, class 3B or 4 laser device, or IPL should be introduced into the Trust without the prior knowledge of the RADIATION PROTECTION ADVISER ("RPA") who can advise on legislative compliance and safety.

12.2 ROLES & RESPONSIBILITIES

12.2.1 General

Overall responsibilities are the same as those in section 4 ARRANGEMENTS AND RESPONSIBILITIES, appendix 1 SPECIFIC REQUIREMENTS FOR MANAGERS, and appendix 2 EMPLOYEES' DUTIES of this Health & Safety at Work Policy.

By law, an employer may not undertake certain practices using IONISING RADIATIONS except in accordance with a prior authorisation granted by the Health & Safety Executive ("HSE"). The HSE must be informed at least 28 days in advance of the first use of IONISING RADIATIONS on a site, except in very rare cases. The Trust's Radiation Physics Department can advise on this matter, and should be consulted before the HSE are contacted

Responsibilities with regard to inspection by regulatory bodies for compliance with radiation regulations are laid down in CP273 POLICY FOR THE MANAGEMENT OF EXTERNAL AGENCY VISITS, INSPECTIONS AND ACCREDITATION.

12.2.2 Departmental Managers

Departmental managers should ensure that the Radiation Physics Department are aware of their uses of IONISING OR NON-IONISING RADIATIONS, and should provide on request all the information required by the Radiation Physics Department to fulfil its duties under this policy.

By law, departments, using IONISING RADIATIONS must consult a Trust appointed, certified RADIATION PROTECTION ADVISER ("RPA") on particular matters, and appoint RADIATION PROTECTION SUPERVISORS ("RPS"). In line with Department of Health ("DH") guidance, departments, using class 3B or class 4 lasers should consult a Trust appointed LASER PROTECTION ADVISER ("LPA"), and appoint LASER PROTECTION SUPERVISORS ("LPS"). See section 12.2.3 below for details.

Departments should ensure that risk assessments are performed for all uses of IONISING & NON-IONISING RADIATIONS, in consultation with relevant RPA, LPA, RPS, LPS's, and that appropriate LOCAL RULES are produced and implemented for the safe use of these radiations. Departments should ensure that staff are adequately trained and supervised.

It is the policy of the Trust that an RPA or LPA is consulted on all IONISING & NON-IONISING RADIATIONS incidents.

By law, the Trust must maintain a list of all equipment which delivers IONISING RADIATION to a patient and equipment which directly controls or influences the extent of such equipment. This equipment inventory must include name of manufacturer, model number, serial number of unique identifier, year of manufacture, and year of installation. Departments should maintain such a list for their equipment, and provide a copy to the Radiation Physics Department.

Departmental managers should appoint RADIATION PROTECTION SUPERVISORS ("RPS") and LASER PROTECTION SUPERVISORS ("LPS") where appropriate, and inform the RPA or LPA of their appointment (see 12.2.6 & 12.2.7).

12.2.3 Radiation Protection Adviser ("RPA") (IONISING RADIATIONS)

By law, the Trust must formally appoint a suitably qualified RPA. RPA's are usually part of the Radiation Physics Department and will be appointed by the Head of Radiation Physics on behalf of the Trust.

By law, the Trust appointed RPA must be consulted on the following radiation protection matters.

- The implementation of requirements as to controlled and supervised areas.
- The prior examination of plans for installations and the acceptance into service of new or modified sources of ionising radiation in relation to any engineering controls, design

features, safety features and warning devices provided to restrict exposure to ionising radiation.

- The regular calibration of equipment provided for monitoring levels of ionising radiation and the regular checking that such equipment is serviceable and correctly used.
- The periodic examination and testing of engineering controls, design features, safety features and warning devices and regular checking of systems of work provided to restrict exposure to ionising radiation.
- Prior risk assessment of new radiation work.
- Incidents where an accidental dose of more than 6 mSv effective dose has been received.
- The critical examination of safety features of newly installed radiation equipment.
- The conduct of any investigation required by the Ionising Radiations Regulations 1999.
- The drawing up of contingency plans for reasonably foreseeable radiation accidents.
- The dose assessment and recording of classified persons.
- Quality assurance programmes for medical radiation equipment or apparatus.

The RPA must hold a current certificate of competence from an HSE approved scheme.

The managers of departments using IONISING RADIATION should also consult the RPA on other matters of radiation safety and legislative compliance when appropriate.

The RPA will advise the Trust on compliance with radiation regulations.

12.2.4 Laser Protection Adviser (“LPA”) and Advice on Other Non-Ionising Radiations

LPA’s for the Trust will be appointed by the head of the Radiation Physics Department. Departments should consult the LPA on the use of all class 3B laser devices (e.g. low level laser therapy units), all class 4 (e.g. surgical) laser devices, and all INTENSE PULSED LIGHT sources (“IPL”). Departments may in some circumstances also wish to consult the LPA on class 3R and other laser devices.

Advice on the safe use of ultraviolet radiation, magnetic resonance imaging, and other NON-IONISING RADIATIONS is available from the Radiation Physics Department

12.2.5 Medical Physics Experts (“MPE”) (IONISING RADIATIONS)

By law, the Trust must ensure that a suitable MPE is involved in every MEDICAL EXPOSURE. An MPE must be -

(a) closely involved in radiotherapy

(b) available in nuclear medicine

(c) involved as appropriate for consultation on optimisation, including patient dosimetry and quality assurance, and to give advice on matters relating to radiation protection concerning medical exposure, as required, in all other radiological practices.

MPE’s for (a) and (c) shall be appointed by the Head of Radiation Physics. MPE’s for (b) shall be appointed by the Head of Nuclear Medicine.

12.2.6 Radiation Protection Supervisors (IONISING RADIATIONS)

By law, departments using ionising radiations (e.g. X-rays, radioactive substances) must appoint one or more suitable RADIATION PROTECTION SUPERVISORS (“RPS) for the purpose of securing compliance with the Ionising Radiations Regulations 1999 (“IRR99”) in respect of work carried out in their department, where LOCAL RULES are required. The names of RPS’s must be set down in the LOCAL

RULES for each CONTROLLED AREA., which should make clear for what areas of work the RPS is appointed.

The RPS should

- Know and understand the requirements of IRR99 and local rules relevant to their area
- Command sufficient authority from the people doing the work to allow them to supervise the radiation protection aspects of that work
- Understand the necessary precautions to be taken and the extent to which these precautions will restrict exposures
- Know what to do in an emergency

Heads of department should inform the Radiation Physics Department of the appointment of each individual as an RPS.

12.2.7 Laser Protection Supervisors (“LPS”)

In accordance with DH guidance, departments using class 3B or class 4 laser devices, OR INTENSE PULSED LIGHT sources (“IPL”) should appoint suitable LASER PROTECTION SUPERVISORS (“LPS”).

The LPS is an individual within the department, who is:

- responsible for supervising the work of personnel who operate optical radiation equipment
- responsible for supervising the optical radiation equipment
- responsible for supervising the LOCAL RULES and ensure that they are followed on a day-to-day basis.

The LPS will liaise with the LASER PROTECTION ADVISER (LPA), equipment users and others.

Heads of department should inform the consultant LPA of the appointment of each individual as an LPS.

12.2.8 Radiation Physics Department

On behalf of the Trust, the Radiation Physics Department will

- Appoint suitable, certified RADIATION PROTECTION ADVISERS (RPA’s)
- Appoint suitable LASER PROTECTION ADVISER LPA(s)
- Appoint MEDICAL PHYSICS EXPERTS (MPE’s) for radiotherapy and radiodiagnosis.

On its departmental internet site

- maintain a list of radiation legislation and national guidance
- publish a list of suggested formal staff DOSE INVESTIGATION LEVELS (DIL)
- publish recommended DIAGNOSTIC REFERENCE LEVELS (DRL) for diagnostic radiology

Provide advice on IONISING and NON-IONISING RADIATION health and safety issues to departments who have notified it of their use of such radiations.

Liaise with enforcement bodies with regard to radiation legislation.

Advise on and provide training, within available resources.

12.2.9 IRMER Roles (IONISING RADIATION)

The Ionising Radiation (Medical Exposure) Regulations 2000 (amended 2006) specify various roles for those participating in the exposure of patients to IONISING RADIATION. By law, the Trust must have procedures to identify individuals entitled to act as REFERRER OR PRACTITIONER OR OPERATOR. With the wide range of uses of medical exposures in the Trust, the most appropriate system is for these procedures to be produced at a departmental level.

12.2.9.1 IRMER Referrer

An "IRMER REFERRER" is a registered health care professional, medical practitioner, dental practitioner or other health professional who is entitled in accordance with a department's procedures to refer individuals for medical exposure to a practitioner.

Departments must produce written procedures for who may act as an IRMER REFERRER and refer patients to their department for medical radiation exposures. Such procedures may restrict to which type of procedure different types of referrers may refer.

Departments must establish recommendations concerning referral criteria for medical exposures, including radiation doses, and must ensure that these are available to their referrers.

By law, the referrer must supply the IRMER PRACTITIONER with sufficient medical data to enable the IRMER PRACTITIONER to decide on whether the medical exposure proposed will provide sufficient net benefit to the patient to be justified.

12.2.9.2 IRMER Practitioner

An "IRMER PRACTITIONER " is registered health care professional medical practitioner, dental practitioner or other health professional who is entitled in accordance with a department's procedures to justify an individual medical exposure. The IRMER PRACTITIONER may issue guidelines allowing IRMER OPERATORS to authorise specific types of medical exposure.

By law, IRMER PRACTITIONERS must be adequately trained and undertake continuing education and training after qualification including, in the case of clinical use of new techniques, training related to these techniques and the relevant radiation protection requirements. The IRMER PRACTITIONERS must comply with departmental IRMER procedures

12.2.9.3 IRMER Operator

An "IRMER operator" is a person who is entitled, in accordance with the Trust/department's procedures, to carry out practical aspects of a medical exposure. This might include radiographers, radiologists, interventional cardiologists, service engineers, medical physics QA staff, etc.

Whether service engineers are included as IRMER OPERATORS will depend on whether they are responsible for approving units as safe to return to clinical service following a repair or modification which affects radiation output (see 12.4.2 Equipment Repairs), or whether this responsibility rests with another OPERATOR, such as a physicist or a radiographer. External service engineers are not usually classed as IRMER OPERATORS. In-house service engineers will only be classified as IRMER OPERATORS where appropriate, and with the written agreement of both the relevant radiation user department and servicing department.

By law, IRMER OPERATORS must be adequately trained and undertake continuing education and training after qualification including, in the case of clinical use of new techniques, training related to these techniques and the relevant radiation protection requirements. They must comply with Trust/departmental IRMER procedures and only carry out a medical exposure if it has been justified by an IRMER PRACTITIONERS, or authorised by an OPERATORS in accordance with guidelines issued by an IRMER PRACTITIONER.

12.3 RADIATION INCIDENTS

See Trust Policy CP129 Managing Hazards And Incidents: Reporting, Investigation And Analysis.

It is the policy of the Trust that a Trust RPA or LPA is consulted on all IONISING OR NON-IONISING RADIATIONS incidents. By law an RPA must be consulted over incidents where an accidental dose of more than 6 millisieverts (mSv) effective dose has been received.

12.4 NEW INSTALLATIONS & EQUIPMENT REPLACEMENT

12.4.1 New Installations & Radiation Emitting Equipment, including loans and trials

The Radiation Protection Adviser (RPA) must be consulted at an early stage on all new installations and replacements of radiation generating equipment, and all new uses of radioactive substances. It is a legal requirement under the Ionising Radiation Regulations 1999 that the RPA is formally consulted on "The prior examination of plans for installations and the acceptance into service of new or modified sources of ionising radiation in relation to any engineering controls, design features, safety features and warning devices provided to restrict exposure to ionising radiation."

In line with DH guidance, the LASER PROTECTION ADVISER (LPA) should be consulted on all new class 3B and class 4 laser devices, and IPL's.

The RPA/LPA will assess the hazards, give advice on room layout, building requirements, choice of equipment, designation of CONTROLLED AREAS, LOCAL RULES, etc. Where necessary, the RPA will notify the HSE of the new work, report special hazard assessments, etc.

All new radiation generating equipment must by law undergo a critical examination, before going into clinical use. This is the legally the responsibility of the supplier, who must consult an RPA. All new equipment should also undergo an acceptance test carried out by the RPA's staff on behalf of the Trust.

Note that "new equipment" includes loans, leases, PFI's, etc. as well as purchases.

Departments should add new equipment which delivers IONISING RADIATION, etc. to their equipment inventory. See 12.2.2.

12.4.2 Equipment Repairs

Before equipment which has been repaired or modified is returned to clinical service a formal handover procedure, detailed in the Local Rules, should be followed. Acceptance of such equipment should always include a functional check by the user, and, if major components affecting ionising radiation output have been modified or repaired, a critical examination by the RPA's staff.

12.4.3 Replacement of Aging Equipment (IONISING RADIATIONS)

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 (DRL's). Departments 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 (e.g. 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.

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

Equipment that is going to be scrapped should be disabled, e.g. 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.

12.5 PERSONAL RADIATION DOSE MONITORING (IONISING RADIATIONS)

12.5.1 Classified Persons

Under the Ionising Radiations Regulations 1999 ("IRR99") employees who are likely to receive an effective dose in excess of 6 millisieverts (mSv) per year, a skin dose in excess of 150 mSv per year, or an eye dose in excess of 45 mSv a year must be designated by the Trust as a CLASSIFIED PERSON.

At the time of drafting this policy, the Trust does not employ any CLASSIFIED PERSONS. However, any decision to classify a person by their manager must be undertaken in consultation with the RADIATION PROTECTION ADVISER (RPA) who can advise on how to comply with the legislation. The radiation doses received by a CLASSIFIED PERSONS must be assessed and records kept until the employee has reached the age of 75 years, and for at least 50 years by an HSE approved dosimetry service.

12.5.2 Other Employees

For employees who are not CLASSIFIED PERSONS direct monitoring is not compulsory. However, the Trust must be able to demonstrate by personal monitoring or other suitable measurements that doses to persons entering controlled areas do not exceed

- For employees, the trigger levels which would require them to become classified persons
- For others (other than those entering the area in order to undergo a medical exposure), the public dose limits

Therefore, in order to monitor the effectiveness of local rules and systems of work, and to help ensure that the annual dose received is less than $\frac{3}{10}$ th of any dose limit, personal dosimeters are issued to selected members of staff. The doses recorded by these dosimeters should be assessed regularly by the head of department, or their delegate who may also be the person appointed as RADIATION PROTECTION SUPERVISOR (RPS).

Most staff working regularly in CONTROLLED AREAS will wear a dosimeter as directed by that area's RPS in accordance with the LOCAL RULES.

12.5.3 Employees Responsibility

The HSE has stated that "employees who persistently fail to wear, look after or return their dosimeters promptly are liable to enforcement action by inspectors up to and including prosecution under Section 7 of the HSW Act 1974." Therefore, cases where employees have acted in this manner may need pursuing through the Trust disciplinary procedure.

By law, employees must not knowingly expose themselves or any other person to a radiation dose greater than is reasonably necessary for the purposes of their work.

12.5.4 Formal Dose Investigation Levels

A formal investigation shall be undertaken when a member of staff receives a dose in excess of the FORMAL DOSE INVESTIGATION LEVEL ("DIL"). Some suggested values of DIL are published by the RPA on the Trust's Radiation Physics website (www.hey.nhs.uk/hullrad). It may be appropriate for individual departments, in consultation with the RPA, to adopt lower DIL's than these or in very exceptional circumstances higher DIL's. Levels adopted must be recorded in the appropriate Local Rules. DIL's cannot exceed annual dose limits.

If a DIL is exceeded, a formal investigation must be undertaken by the head of department, or a suitable person appointed by the head of department. This investigation should be carried out in

consultation with the RPA, and include the RPS for the area concerned. The RPS should also investigate where doses are in excess of normal values for that group of staff and report to the head of department. The results of any formal investigation should be recorded. Where a high dosimeter reading is the result of a lost or damaged dosimeter, this should be recorded by the RPS.

12.6 PREGNANCY & BREASTFEEDING FOR STAFF WORKING WITH IONISING RADIATION

12.6.1 Background

The requirements detailed below are in addition to those in section 8. *NEW AND EXPECTANT MOTHERS AT WORK POLICY*, and do not replace the requirements of that section.

Members of staff working with X-ray equipment and radioactive substances are naturally concerned to minimise any risk to a foetus should they become pregnant. The Ionising Radiations Regulations 1999 (IRR99) specifically identify the need for adequate information, placing an onus on the employer to provide information and on the employee to report a pregnancy.

(Note, there are no specific risks to the foetus associated with the use of medial lasers or ultraviolet radiation)

12.6.2 Legal Requirements

The employer must

- in relation to pregnant employees, ensure that the dose to the foetus is unlikely to exceed 1 millisievert (mSv) after they are notified of the pregnancy
- in relation to breastfeeding employees who work with radioactive substances, ensure that the conditions of exposure are restricted so as to prevent significant bodily contamination of that employee
- notify female employees working with ionising radiation of the possible risks to a foetus from radiation, and the importance of informing the employer in writing as soon as possible after they become pregnant
- notify female employees working with radioactive substances of the possible risks to a nursing infant from contamination, and the importance of informing the employer in writing if they are breastfeeding.

12.6.3 Doses and Risk to the Foetus

The current legal limit of dose to the foetus, from the time pregnancy is declared to term is 1 mSv, which corresponds to a dose to the woman's abdomen from X-rays of around 2 mSv. If we assume eight months of declared pregnancy, the dose must be kept below an average of 0.25 mSv per month for that eight month period.

Personal monitoring over many years has shown that this level is well below the dose received by virtually all staff, providing that the *LOCAL RULES* are followed.

It should be noted that the "dose limits" do not imply that exposures above these limits will necessarily cause any harm. Severe effects (such as malformation or foetal death) only occur if the foetus is exposed to hundreds of millisieverts in a short period of time. Smaller doses of radiation can increase the risk of childhood cancer by a small amount. The natural risk of fatal childhood cancer is 1 in 1,300. The risk of radiation induced childhood cancer from 1 mSv is around 1 in 17,000, more than ten times less than the natural risk.

12.6.4 Conclusions

Staff working with x-rays or radioactive materials should inform their line manager as soon as they learn that they are pregnant.

In almost all circumstances, there are no grounds for amending staff working practice during pregnancy.

The manager should, however, consider whether changes are necessary in working practice, on the basis of previous personal dose badge results.

If there are any questions or doubts, then contact a radiation protection adviser (RPA) in the Radiation Physics Department, CHH (01482 761375)

12.7 PATIENT PREGNANCY & IONISING RADIATION

12.7.1 Diagnostic Procedures

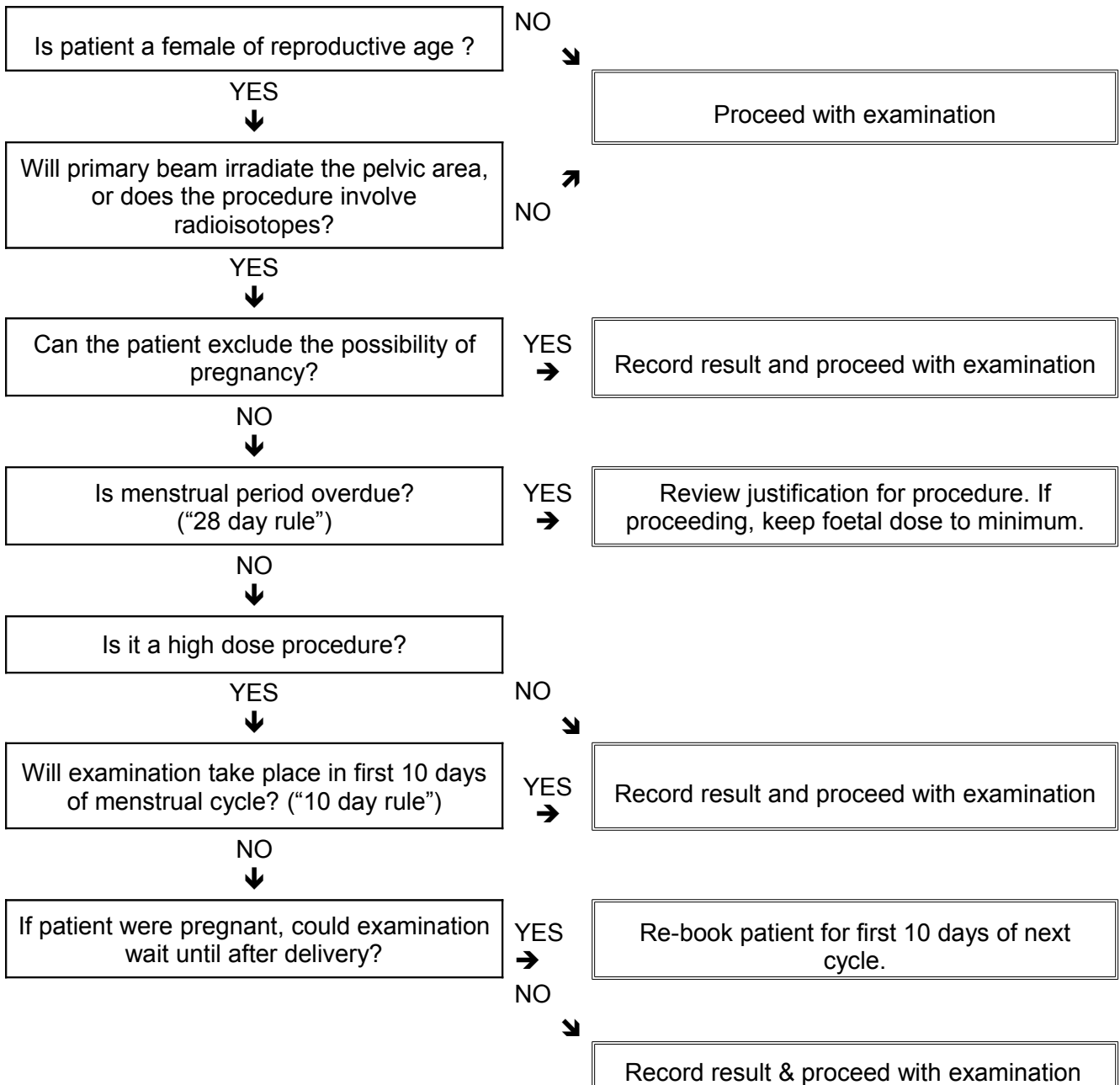
12.7.1.1 Introduction

- In all women of reproductive capacity, the clinician requesting the examination should consider the possibility of pregnancy.
- The latest national guidelines acknowledge that there is no risk to the conceptus following irradiation during the first 10 days of the menstrual cycle. However, in the interval between 10 days and the date at which the next menstrual cycle is due there is a small risk for high dose procedures such as pelvic or abdominal CT and barium enemas.
- If a foetus has been inadvertently exposed, the Radiation Protection Adviser should be informed. He can then provide a dose and risk estimate.
- At diagnostic dose levels, the only adverse effect of radiation on the conceptus is an increased risk of cancer induction. Dose levels are too low to induce death or malformations. Therefore, invasive foetal diagnostic procedures or termination of the pregnancy are not justified.
- The accompanying flow diagram indicates the general procedure to be followed. Where necessary Local Rules should give any specific requirements for particular work areas.
- The superintendent radiographer **or equivalent** is responsible for ensuring that all staff are familiar with the correct procedure, and that normal good radiographic practice is carried out to ensure that radiation doses are kept as low as is reasonably achievable.

12.7.1.2 Particular Advice on Establishing Whether Patient May Be Pregnant

- In order to ensure that the examination is carried out within 28 days of the last menstrual period (LMP) patients should be asked, "*Are you or may you be pregnant?*" or "*Is your last menstrual period overdue?*" To assist in obtaining correct information the following precautions should be taken:-
 - a) Advisory notices should be prominently displayed in X-ray **& nuclear medicine** departments.
 - b) X-ray **and nuclear medicine** request forms should have a space to allow for insertion of the LMP by the referring clinician.
 - c) The examining operator (*e.g. radiographer, medical physicist or technician*) to check the dates of LMP especially if there is a long delay between request and exposure.
- If the operator does not obtain satisfactory assurance the request should be referred back to the requesting clinician or department, or to a radiologist.
- This advice may be ignored in the following cases:-
 - a) Women who have been on the contraceptive pill/implant/injection for three months or more, or have an IUD fitted.
 - b) Women who have been sterilised.
 - c) Nuns.
 - d) Women who are outside the age range of 12 - 50 or are post menopausal.

12.7.1.3 General Procedure To Prevent Unnecessary Exposure Of The Foetus



12.7.2 Therapeutic Procedures

Ionising radiations are used for treatment in oncology, endocrinology, and palliative treatments of pain relief. In all women of reproductive capacity, the clinician requesting the therapeutic radiation dose should consider the possibility of pregnancy, both at time of prescription and at the time that the dose is to be administered. The final decision will rest with the prescribing clinical oncologist or ARSAC license holder (i.e. the IRMER practitioner)

12.8 “IRMER PROCEDURES” & PROTOCOLS FOR MEDICAL EXPOSURES (IONISING RADIATIONS)

12.8.1 Minimum Set of IRMER PROCEDURES

The Ionising Radiation (Medical Exposures) Regulations 2000 (amended 2006) (“IRMER”) require the Trust to have a minimum set of written procedures for medical exposures (“IRMER PROCEDURES”).

Samples of some of these procedures can be downloaded from the Radiation Physics website (www.hey.nhs.uk/hullrad). Each department undertaking medical exposures is responsible for ensure that IRMER PROCEDURES are in place for their activities. Advice may be sought from the Radiation Physics department on producing IRMER PROCEDURES.

A department’s IRMER PROCEDURES must include procedures –

- (a) to identify correctly the individual to be exposed to ionising radiation;
- (b) to identify individuals entitled to act as REFERRER OR PRACTITIONER OR OPERATOR;
- (c) to be observed in the case of medico-legal exposures;
- (d) for making enquiries of females of childbearing age to establish whether the individual is or may be pregnant or breastfeeding;
- (e) to ensure that quality assurance programmes are followed;
- (f) for the assessment of patient dose and administered activity;
- (g) for the use of diagnostic reference levels established by the employer for radiodiagnostic examinations falling within the categories diagnosis, occupational health surveillance, health screening programmes and medico-legal procedures, specifying that these are expected not to be exceeded for standard procedures when good and normal practice regarding diagnostic and technical performance is applied;
- (h) for determining whether the practitioner or operator is required to effect one or more of the matters set out in regulation 7(4) including criteria on how to effect those matters and in particular procedures for the use of dose constraints established by the employer for biomedical and medical research programmes falling within regulation 3(d) where no direct medical benefit for the individual is expected from the exposure;
- (i) for the giving of information and written instructions as referred to nuclear medicine patients or their guardians
- (j) for the carrying out and recording of an evaluation for each medical exposure including, where appropriate, factors relevant to patient dose;
- (k) to ensure that the probability and magnitude of accidental or unintended doses to patients from radiological practices are reduced so far as reasonably practicable.

12.8.2 IRMER Protocols

IRMER requires that the Trust ensure that written protocols are in place for every type of standard radiological practice for each equipment. Each department undertaking medical exposures is responsible for ensure that such written protocols are in place.

DH guidance clarifies that protocols cannot be absolute or totally comprehensive as it is not possible to produce detailed and rigid protocols for every examination. However, they should be specific to each examination and machine as appropriate, e.g. in diagnostic practice, for a particular x-ray room, x-ray exposure factors for a specific examination (PA chest: 120kV 2mAs). They must be written down and their status clear. Protocols should allow latitude for professional judgment but where the latitude provided is exceeded and exposure factors varied, it would be advisable to record the changes made. Where, on commissioning, exposure values are programmed via the console into the x-ray generator, it is recommended that a record of the

values be kept in the department together with any changes to these values, whether for individual patients, or as a result of agreed protocol changes.

In radiotherapy, the protocols might refer to standard dose regimes, energies and beam projections and may be specific to each consultant if necessary. Such protocols would not negate the need for individual planning to produce the intended therapeutic effect.

12.9 CO-OPERATION BETWEEN UNIVERSITY OF HULL AND HULL & EAST YORKSHIRE HOSPITAL NHS TRUST (IONISING RADIATIONS)

NOTE – Slight change (1985 regs to 1999, name of Trust) from previous agreement – emailed to Univ Rad Safety Comm to approval

12.9.1 Introduction

A number of academic staff have routine NHS sessional commitments. Some project work is also undertaken by academic staff on NHS Trust premises.

The Ionising Radiations Regulations 1999, regulation 15 states,

“Where work with ionising radiation undertaken by one employer is likely to give rise to the exposure to ionising radiation of the employee of another employer, the employers concerned shall co-operate by the exchange of information or otherwise to the extent necessary to ensure that each such employer is enabled to comply with the requirements of these Regulations in so far as his ability to comply depends upon such co-operation.”

12.9.2 Implementation

- a) In general, staff will adopt the safety policies and procedures of the employer upon whose site they are working.
 - b) Dose monitoring of medical staff for NHS sessions will be carried out through the NHS user departments and copies of the annual report of the Trust's Radiation Protection Adviser shall be submitted to the University Safety Committee and University Safety Officer. Any exposure or potential increase in exposure likely to result in designation of the employee as a classified worker, or other untoward occurrences will be discussed with the health service Radiation Protection Adviser and University Safety Officer forthwith.
 - c) Projects on NHS premises involving exposure of staff to ionising radiation should be discussed with the health service Radiation Protection Adviser and University Safety Officer in advance so that an appropriate and consistent monitoring policy can be instituted.
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12.10 EMPLOYEES OF OTHER EMPLOYERS (IONISING RADIATIONS)

12.10.1 General Requirements

By law, where work with ionising radiation undertaken by one employer is likely to give rise to the exposure to ionising radiation of the employee of another employer (e.g. service engineer, visiting staff), the employers concerned shall co-operate by the exchange of information or otherwise to the extent necessary to ensure that each such employer is enabled to comply with the requirements of the Ionising Radiations Regulations 1999 (“IRR99”) in so far as his ability to comply depends upon such co-operation.

12.10.2 Controlled Areas & Local Rules

When an external service engineers undertake servicing or repair of sources of ionising radiation (e.g. X-ray sets) in an area designated by a Trust department as a CONTROLLED AREA then it may be appropriate

(a) for the engineer to follow the LOCAL RULES issued by the Trust department for that CONTROLLED AREA, or

(b) for a formal temporary handover of the CONTROLLED AREA to the service engineer. All persons entering that CONTROLLED AREA must then follow LOCAL RULES issued by the servicing company. When the service engineer has completed his work, the CONTROLLED AREA should then be formally returned to the department, and the department’s LOCAL RULES followed.

All departments using sources of ionising radiation should consider which option is appropriate in consultation with the external companies in question, and document the department’s policy.

12.10.3 CLASSIFIED PERSONS From Another Employer – “OUTSIDE WORKERS”

IRR99 defines “OUTSIDE WORKERS” as “a CLASSIFIED PERSON who carries out services in the controlled area of any employer (other than the controlled area of his own employer)”. Examples might include

- An X-ray manufacturer service engineer working in our Trust’s X-ray rooms
- A radiopharmacist from another Trust visiting our Trust’s Nuclear Medicine Department.

However, most X-ray engineers are not CLASSIFIED PERSONS and therefore not IRR99 OUTSIDE WORKERS

Where an OUTSIDE WORKER is to enter one of our CONTROLLED AREAS, then the Trust must ensure that

(a) the OUTSIDE WORKER is subject to arrangements for estimating the dose of ionising radiation he receives whilst in the CONTROLLED AREA;

(b) as soon as is reasonably practicable after the services carried out by that OUTSIDE WORKER in that controlled area are completed, an estimate of the dose received by that worker is entered into his radiation passbook; and

(c) when the radiation passbook of the OUTSIDE WORKER is in the possession of that employer, the passbook is made available to that worker upon request.

12.11 CONTROL OF RADIOACTIVE SUBSTANCES

12.11.1 Introduction

The holding, using and disposing of radioactive substances is controlled by the Radioactive Substances Act 1993 ("RSA93") and its various exemption orders. The transport of radioactive substances is controlled by The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations ~~2007~~. ("CDG07") ~~2009~~ ("CDG09").

Radioactive materials may not be held and used unless registered under section 7 or 10 of the Act, or exempt from registration. Radioactive waste may not be disposed or waste accumulated unless authorised under sections 13 and 14 of the Act, or exempt from authorisation. It should be noted that exemption orders often contain their own specific conditions and requirements.

12.11.2 Responsibilities

The department holding radioactive substances is responsible for their safe use^d, and compliance with all relevant legislation. Advice on health, safety, and legislation is available from the RADIATION PROTECTION ADVISER (RPA) who should be consulted when any new process is considered. The head of the department will appoint a suitable radioactive source custodian, and inform the Radiation Physics Department of their appointment.

Each radioactive source custodian will supervise the keeping and use of their department's radioactive sources. The name of the each radioactive source custodian will be displayed in their department with a copy of any RSA93 certificates.

12.11.3 RSA93 Certificates

Certificates are issued by the Environment Agency for sites and not for individual departments. Therefore, departments and their radioactive source custodian must co-operate with the Radiation Physics Department to ensure that site wide limits are not breached.

Applications for changes to RSA93 authorisation and registrations may only be made by the Nuclear Medicine Department and the Radiation Physics Department. Both departments must see and approve an application before it is submitted to the Environment Agency.

The control of radioactive substances will normally be delegated to the radiation protection supervisor.

12.12 COMFORTER & CARERS and Others Exposed Via the Medical Exposure of Another Person (IONISING RADIATIONS)

12.12.1 Who are COMFORTER AND CARERS?

Under the Ionising Radiations Regulations 1999 ("IRR99"), "COMFORTERS AND CARERS" are defined as

"individuals who (other than as part of their profession) knowingly and willingly incur an exposure to ionising radiation in the support or comfort of another person who is undergoing, or has undergone a medical exposure".

The definition does not include nurses, radiographer, staff accompanying residents of nursing homes, etc. as these persons are acting in a professional capacity.

COMFORTER AND CARERS may include members of the public who, for example

- visit patients in hospital after those patients have been administered with radiopharmaceuticals or are undergoing brachytherapy
- offer support for those patients at home who have undergone certain nuclear medicine procedures, or had sealed sources permanently implanted
- (in some cases) offer support to a young child or disabled person while that person is X-rayed

and are likely to receive more than the public dose limit of 1 mSv a year resulting from direct radiation or contamination during the comfort and support they offer.

If they are unlikely to receive more than 1 mSv a year then they need not be classified as COMFORTER AND CARERS under IRR99. IRR99 also allows a separate dose limit for persons who may be exposed to radiation resulting from the medical exposure of another. This limit is 5 mSv in 5 years. This limit is designed for friends and family, including children, who may not be aware of being exposed, or able to give consent. This provision is aimed mainly at the nuclear medicine patients.

12.12.2 Action Required for COMFORTER AND CARERS

There is no dose limit for COMFORTER AND CARERS, but it is appropriate to apply DOSE CONSTRAINTS.

The general dose constraint will be 5 mSv for COMFORTERS AND CARERS. Procedures should be designed that will keep doses to COMFORTER AND CARERS below this level.

Staff should satisfy themselves that COMFORTER AND CARERS are aware of the risks involved in supporting and comforting a patient and are willing to incur the exposure they will receive. These arrangements may involve effective communications with the patient or directly with the COMFORTER AND CARER. The information needed will depend upon the particular circumstances of the exposure.

As with all persons, doses to COMFORTER AND CARERS must be kept as low as reasonably practicable, and must never exceed the dose constraints defined below. Consider time, distance, and shielding.

Lead-rubber aprons and other shielding should be utilised wherever practical.

Pregnant women should not normally act as COMFORTER AND CARERS, however for circumstances where this is appropriate, a dose constraint of 1 mSv should be applied.

12.12.3 Exceptional Circumstances

In most cases, COMFORTER AND CARERS would normally be expected to keep to the arrangements for keeping their dose as low as is reasonably achievable, and below the dose constraint. However, they may choose to depart from them, for example by spending more time with a seriously ill patient than is recommended, thereby incurring a dose greater than 5 mSv. This is perfectly reasonable provided that they do so willingly and are aware that they may incur a small additional

risk from this increased exposure. [IRR99 Approved Code of Practice and Guidance (2000), para. 131]

12.13 QUALITY ASSURANCE AND AUDIT (IONISING RADIATIONS)

12.13.1 Introduction

The Ionising Radiation Regulations 1999 (“IRR99”) and the Ionising Radiation (Medical Exposure) Regulation 2000 (IRMER) impose requirements for quality assurance programmes for the medical
USE OF IONISING RADIATION.

12.13.2 Equipment

Departments will have in place a regular programme of tests for equipment which affects radiation dose to staff or patients. The RPA and relevant MPE should be consulted on the contents of this programme. Frequency of testing and acceptable ranges of results will be in line with accepted national standards.

All X-ray equipment will include testing by the Radiation Physics Department at least annually, as well as more frequent user testing. Acceptance testing will be carried out for all new X-ray emitting equipment, and following major repair/replacement which may affect dose to patients, staff or others, or affect image quality.

All instruments used for the assessment of dose should be tested at least annually.

12.13.3 Standard Operating Procedures

Departments must ensure that agreed working practices are maintained and any discrepancy reported to the Service Manager. Departments must have a quality assurance programme for the auditing of IRMER procedures.

Auditing of regulatory compliance may include auditing by the Radiation Physics Department.

12.14 PROCEDURE FOR USE OF DIAGNOSTIC REFERENCE LEVELS (“DRL”) FOR RADIODIAGNOSIS (IONISING RADIATIONS) (IRMER PROCEDURE g)

12.14.1 Introduction

The Ionising Radiation (Medical Exposure) Regulations 2000 (“IRMER”), requires a procedure for the establishment of DIAGNOSTIC REFERENCE LEVELS (“DRL”) for radiodiagnostic examinations. This section fulfils this requirement.

12.14.2 Setting Diagnostic Reference Levels

Guidance from the Royal College of Radiologist states that DRL need not be set for radiotherapy planning exposures. For other routine imaging procedures using ionising radiation, DRL’s should be set by each relevant department.

12.14.2.1 National Diagnostic Reference Levels (“NDRL”)

NDRL’s have been described as “essentially a guide to the rather indistinct borderline between ‘good and normal practice’ and ‘bad and abnormal practice’.” (IPEM Report 88)

National DRL’s for nuclear medicine imaging are published by ARSAC.

Recommendations for national DRL’s for diagnostic radiology come from various bodies. The Radiation Physics Department will publish these on their website (www.hey.nhs.uk/hullrad)

12.14.2.2 Diagnostic Reference Levels (“LDRL”)

Where LDRL’s have not yet been determined, the LDRL will equal the NDRL.

LDRL’s will be established by departments when sufficient dose data is available to establish typical dose levels in their departments. LDRL’s are particularly useful where local dose levels are already significantly below NDRL’s, as a means of monitoring changes in dose levels.

The Radiation Physics Department will assist departments in the establishment of LDRL’s. Department should always inform the Radiation Physics Department of any changes in their DRL’s

12.14.3 Periodic Patient Dose Assessment

NDRL’s are not expected to be exceeded for standard procedures when good and normal practice, regarding diagnostic and technical performance, is applied. Departments must check this using periodic patient dose assessments (*or “dose survey”*) of a representative group of patients.

If the average dose from a periodic patient dose assessment is greater than the DRL then the department performing the medical exposures should investigate the reason for this and initiate corrective action where appropriate. Records of all survey results and investigations should be kept.

Guidance on undertaking periodic patient dose assessments can be obtained from the Radiation Physics Department.

12.15 TRAINING & TRAINING RECORDS

It is the responsibility of departments to ensure that their members of staff are adequately trained. The Radiation Physics Department can provide advice on training, and in some cases provide the appropriate training in-house.

12.15.1 Lasers / Intense Pulsed Light Sources (“IPL”)

12.15.1.1 Authorised Operators (also known as authorised users)

The AUTHORISED OPERATOR is the individual who operates the laser or IPL.

Laser may only be operated by AUTHORISED OPERATOR, or in special circumstances by other persons under the direct supervision of an AUTHORISED OPERATOR. AUTHORISED OPERATOR should be classed as clinical (e.g. surgeons) or non-clinical (e.g. maintenance staff).

The AUTHORISED OPERATOR’s manager, LPS or LPA will specify and assess the level of competence required. The AUTHORISED OPERATOR will have received suitable laser/IPL equipment training. They should also have attended an appropriate safety course. The Authorised User must be knowledgeable in how to operate the particular device, how the controls will effect the treatment and the LOCAL RULES for the safe use of that particular device.

The AUTHORISED OPERATOR is responsible for using the laser in a safe manner for both staff and patients. The AUTHORISED OPERATOR should see that eye protection is worn by staff where this is laid down in the LOCAL RULES.

A register of AUTHORISED OPERATOR of Class 3B or 4 lasers and IPL systems should be held by the LASER PROTECTION SUPERVISOR (LPS)

12.15.1.2 Authorised Assistant

Some lasers require a second person to assist the AUTHORISED OPERATOR. For example, most surgical lasers require an assistant to operate the laser console while the surgeon controls the fibre optic, or other delivery system, and a footswitch which fires the laser. The responsibilities of the AUTHORISED ASSISTANT should be detailed in the LOCAL RULES. These duties may include ensuring that all members of staff in the CONTROLLED AREA have goggles, ensuring that warning signs are displayed at entrances, preparing the laser for use, etc.

AUTHORISED ASSISTANTS should have received training on general laser safety, and should normally have assisted in at least five or six treatments under the supervision of a previously trained AUTHORISED ASSISTANT. A list of AUTHORISED ASSISTANTS should be kept by the LPS.

12.15.1.3 Others

General laser safety training is provided by the Radiation Physics Department. Depending on the nature of the laser/IPL used, departments should decide which members of their staff who work in laser CONTROLLED AREAS should attend this course.

Members of staff working in laser CONTROLLED AREAS should read the LOCAL RULES for those areas, and sign a record that they have read, understood and will follow them.

12.15.2 Ionising Radiation

12.15.2.1 Staff & Public Safety - Ionising Radiations Regulations 1999 (“IRR99”)

Members of staff engaged in work with ionising radiations must be given appropriate training in the field of radiation protection. Members of staff working in CONTROLLED AREAS should read the LOCAL RULES for those areas, and sign a record that they have read, understood and will follow them.

Radiation protection supervisors should attend an RPS course prior to appointment, or at the earliest opportunity.

12.15.2.2 Patient Safety – Ionising Radiation (Medical Exposure) Regulations 2000 (“IRMER”)

By law, all IRMER PRACTITIONERS and OPERATORS must be adequately trained and undertake continuing education and training after qualification including, in the case of clinical use of new techniques, training related to these techniques and the relevant radiation protection requirements. The Radiation Physics Department can provide advice on adequate training, and provide a portion of that training.

By law, the Trust must keep and have available for inspection by the Healthcare Commission an up-to-date record of all training undertaken by all PRACTITIONERS and OPERATORS engaged by him to carry out medical exposures or any practical aspect of such exposures showing the date or dates on which training qualifying as adequate training was completed and the nature of the training. The task of compiling and keeping such records is delegated to head of department. Records must be kept for all staff, both medical and non-medical.

12.16 STAKEHOLDERS

The following stakeholders should be consulted when revising this policy

- Safety Manager, RPA's, LPA's, Health & Safety Committee, JNCC
- Departmental managers, RPS's, LPS's, and service managers for the following departments
 - Radiology Department (X-ray)
 - Radiotherapy Department (X-ray, radioactive substances)
 - Nuclear Medicine Department (X-ray, radioactive substances)
 - Radiation Physics Department (lasers, UV, X-ray, radioactive substances)
 - Bioengineering Department (lasers, UV, X-ray)
 - Plastics Department (X-ray)
 - Theatres – Plastics, Orthopaedics, Gynaecology, Urology, Cardio-thoracic, Breast, ENT (X-ray, class 4 lasers, radioactive substances)
 - Breast Screening (X-ray)
 - Dermatology (UV)
 - Physiotherapy (class 3B lasers)
 - Academic Cardiology (class 3B laser)

Abbreviations used

ARSAC	Administration of Radioactive Substances Advisory Committee
CHH	Castle Hill Hospital
CT	Computed tomography
DH	Department of Health
DIL	Formal dose investigation level
DRL	Diagnostic reference level of dose
e.g.	Exempli gratia
HSE	Health & Safety Executive
IPL	Intense pulsed light source
IRMER	Ionising Radiation (Medical Exposure) Regulations 2000 (amended 2006)
IRR99	Ionising Radiations Regulations 1999
IUD	Intrauterine device
LMP	Last menstrual period
LPA	Laser protection adviser
LPS	Laser protection supervisor
MPA	Medical Physics Expert
mSv	millisieverts
NAIR	National arrangements for incidents involving radioactivity
PFI	Private finance initiative
RPA	Radiation protection adviser
RPS	Radiation protection supervisor

