Leaflet 26

Medical Diagnostic X-ray Equipment

CONTENTS

NOTE

The instructions in this Leaflet apply to MOD units and establishments; they do not apply within Ministry of Defence Hospital Units where responsibility for health and safety in general and radiation safety in the particular context of this publication, rests with the Chief Executive of the NHS Trust concerned.

Scope

1 This Leaflet covers medical diagnostic X-ray equipment (including fluoroscopes). The following information describes the requirements for keeping and using such equipment. Summaries of the radiation risks and regulatory requirements for such equipment are included in the Annexes of this Leaflet.

Statutory Requirements

2 In addition to the general requirements of the Health and Safety at Work etc Act 1974 and the Management of Health and Safety at Work Regulations 1999, the following specific legislation applies directly:

- Ionising Radiations Regulations 1999 (IRR99);
- Ionising Radiation (Medical Exposures) Regulations 2000 (IRMER2000).

Duties

Commanding Officer and Head of Establishment (CO/HoE)

3 The CO/HoE has a duty to the Secretary of State, and a personal responsibility, to protect the environment and secure the health, safety and welfare of their staff at work. The CO/HoE is also required to protect persons not in MOD employment (e.g. members of the public) against risks to their health and safety arising from the MOD work activities. This includes radiation safety. In regard to equipment used for medical exposure, it must be ensured that such equipment is designed, installed and maintained so far as is reasonably practicable to restrict the exposure of any person undergoing a medical exposure to the extent that this is compatible with the intended purpose. The CO/HoE's authority (but not responsibility) for radiation safety management arrangements may be delegated to appropriate personnel, such as a Radiation Safety Officer (RSO).

Radiation Safety Officer (RSO)

4 The Radiation Safety Officer (RSO) is to ensure that they are familiar with the specific radiation hazards at their unit or establishment, and that adequate radiation protection arrangements are made to minimise the radiation hazard including the drawing up of local orders for radiation safety and the issue of local rules, instructions and procedures.

Radiation Protection Supervisor (RPS)

5 The RPS is to ensure that X-ray equipment is correctly used in accordance with local orders for radiation safety including local rules, instructions and procedures. The RPS is also to ensure that reporting procedures for any incidents are followed (see Annex A to this leaflet and also Leaflet 14). The RPS is normally the superintendent radiographer within the department, and should be appropriately trained for the role. This is normally through successful completion of the RPS (X-ray) course at HMS Sultan, details of which can be obtained from the RPA. This training should be refreshed at least every five years.

Practitioners, operators and referrers

6 Practitioners, operators and referrers have specific duties under IRMER2000. Further information on these duties is contained within Annex A.

Employees

7 It is the responsibility of all employees to ensure that X-ray equipment and personal protective equipment is used correctly and not deliberately misused or interfered with and that work is carried out in accordance with local orders, instructions and procedures. Any incidents are to be immediately reported to the RPS.

Hazard

Table 1 Hazard

Radiation type		Emitted	Comments
Alpha		×	
Beta	Direct	×	
	Bremsstrahlung	×	
Gamma		×	

X-rays	✓	X-ray sets generate an in beam exposure hazard. In addition, radiation from X-ray head leakage and scatter from the beam may affect areas around the X-ray head and beam.
Neutrons	✗	

Legal and MoD Mandatory Requirements

Table 2 Legal and MOD mandatory requirements

Requirement	Applicable	Comments	Related Leaflet*
HSE authorisation	✗		
HSE notification	✓		3
Environment agencies notification**	✗		
Risk assessment	✓		2
Restriction of exposure	✓	Restriction of exposure is addressed in Leaflet 4 and local orders in Leaflet 16.	4, 16
PPE	✓	PPE is covered in general in Leaflet 4. See also Annex A of this leaflet for specific guidance for medical PPE.	4
Maintenance of radiation engineering controls	✓	Tests for correct function of: mains on and exposure indication, automatic exposure termination at end of set time and on release of exposure button; room warning lights.	4
Contingency plans	✓	See Leaflet 40	40
Designated areas	✓	Designated areas are required and are covered in general in Leaflet 4. See Annex A of this leaflet for detailed guidance.	4
Monitoring	✗		
Training for users	✓	See Annex A of Leaflet 26 for IRMER2000 training requirements and Leaflet 15 for RPS and user training requirements.	15
Local orders	✓	See Leaflet 16 for guidance on the requirements of local orders and the requirements of IRR99 for local rules.	16
Appointed person	✓	RPS required	3
Storage	✗		
Accounting	✓	X-ray equipment to be recorded on Dstl Annual Holdings Return (copy retained for 1 year) and for IRMER2000 purposes, see Annex A of Leaflet 26.	9
Leak testing	✗		
Personal dosimetry	✓	Whole body dosimeters are to be worn by staff routinely involved with radiology procedures. It may also be necessary to monitor doses to the extremities/thyroid/eye depending on the type and amount of X-ray work being carried out.	6
Reporting procedures	✓	See Leaflet 14 and Annex A of this leaflet for further guidance on the reporting of incidents.	14
Transport	✗		
Disposal	✓	Return to stores.	
Sale/Transfer	✓		
Ionising Radiation (Medical Exposure) Regulations (IRMER 2000)	✓	See Annexes of this leaflet.	-

*JSP 392, unless otherwise stated
**Environment Agency (EA) for England and Wales, Scottish Environment Protection Agency (SEPA) for Scotland and Environment and Heritage Service for Northern Ireland (EHSNI).

This page is intentionally blank

Leaflet 26 Annex A

Specific Requirements and Recommendations for Use of Medical Diagnostic X-ray Equipment

CONTENTS

References

A Medical and Dental Guidance Notes, Prepared by Institute of Physics and Engineering in Medicine, 2002 ISBN 1 903613 09 4

B Ionising Radiation (Medical Exposure) Regulations 2000

C Making the Best Use of Clinical Radiology Services, Referral Guidelines, Seventh Edition, 2012 The Royal College of Radiologists.

D Institute of Physics and Engineering in Medicine (IPEM) Report 91, Recommended Standards for the Routine Performance Testing of Diagnostic X-ray Imaging Systems 2005.

E Doses to Patients from Radiographic and Fluoroscopic X-ray Imaging Procedures in the UK – 2010 Review HPA-CRCE-034 (2012)

Radiation Safety Assessment for New or Refurbished Facilities

1 For new or refurbished X-ray facilities the RPA is to be consulted at the design stage to ensure that design of the facility, including any shielding required, is sufficient to keep doses to personnel as low as reasonably practicable. General guidance on design of radiology facilities is given in Reference A.

Acceptance Testing of New X-Ray Equipment

2 Acceptance tests are to be carried out as advised by the RPA on all newly installed medical X-ray equipment and when an X-ray tube is replaced to ensure that radiological functions are satisfactory and to specification.

3 Medical X-ray sets are to be designed, constructed and installed in accordance with British Standard 60601. Guidance on design, construction and installation of medical X-ray sets is given in Reference A.

4 All new installed X-ray equipment is to be fitted with a dose area product (DAP) meter.

Critical Examination and Design of New X-Ray Facilities

5 A critical radiation safety examination including an assessment of the adequacy of room shielding is to be carried out as advised by the RPA on all new or structurally modified X-ray rooms prior to being brought into routine use.

Controlled and Supervised Areas

6 General requirements relating to controlled and supervised areas are contained in Leaflet 4.

7 A dedicated X-ray room containing installed X-ray equipment is designated as a controlled radiation area during exposures.

8 For mobile X-ray sets, the controlled radiation area extends in the direction of the X-ray beam until the beam is sufficiently attenuated by distance or shielding (e.g. solid floor or wall) and out to 3 metres in all other directions.

Exposure Protocols

9 Written protocols are to be in place for each type of standard radiological practice and for each type of X-ray equipment. For radiography equipment this will involve noting exposure factors, focus to film distance, grid use and automatic exposure control (AEC) use as appropriate for each type of examination. For fluoroscopy equipment the protocol is to include, e.g. collimation, magnification and dose settings. Where exposure settings are programmed into the console, these are to match the values in the exposure chart. Exposure settings are normally recorded in the form of an exposure chart, which is to be signed and dated by a responsible person.

10 After each examination, a record of exposure factors, DAP meter reading or exposure time is to be made in the patient's notes.

11 In the case of fluoroscopic devices, viewing facilities are to be provided which do not permit direct vision of the fluoroscopy screen.

Practitioners, Operators and Referrers

12 Reference B requires that each individual medical exposure is justified by an IRMER practitioner and any practical aspect associated with the exposure carried out by an IRMER operator.

13 In MOD medical facilities, the role of IRMER practitioner and responsibility for justifying medical X-ray exposures normally lies with DCA Radiology. Justification is effected through radiography protocols and guidelines issued by DCA Radiology and implemented by authorisation of the radiographer for each medical exposure.

14 Requests for a radiological examination are initiated by the referrer i.e. any registered medical or dental practitioner or other health professional who is entitled to refer individuals for medical exposure to an IRMER practitioner.

Training

15 Adequate training in the radiation protection of patients, as defined at Reference B, is required for IRMER practitioners and IRMER operators. Adequate training is obtained during professional training and qualification, or a MOD recognised course together with practical experience, mentoring and continuing education and training as appropriate.

16 In most circumstances, adequate training will be met by satisfying the requirements of the appropriate professional bodies, i.e. the Royal College of Radiologists and the College of Radiographers.

17 Each establishment or unit is to maintain a register of adequate training for IRMER practitioners and IRMER operators providing details and dates of training undertaken.

Employer's Procedures for Patient Protection

18 Written standard operating procedures for the radiation protection of patients are to be provided. The written procedures are to include the matters set out at Annex B and are to be signed by the Head of Establishment.

Referral Criteria

19 Referral criteria for medical exposures, including information on radiation doses to patients, are to be made available to those health professionals who refer patients for radiological examination. In MOD medical X-ray departments, referral criteria normally take the form of the RCR Guidelines at Reference C.

Quality Assurance and Patient Dose Assessment

20 All units and establishments are to operate a quality assurance (QA) programme for medical X-ray, film processing and CR equipment. The QA programme is to include routine equipment tests carried out by department staff and annual/biennial tests by medical physicists. Guidance on QA tests is provided at Reference D or may be obtained from the RPA.

21 The QA programme is to include an assessment of radiation doses received by patients from different types of examination. This will normally be carried out by the RPA/physicist on the basis of exposure information provided by the department. Patient doses will be used for comparison with diagnostic reference levels (DRLs) such as the national DRLs available at Reference E.

Personal Protective Equipment

22 X-ray personal protective equipment (PPE) for staff includes aprons, gloves and thyroid shields incorporating lead to reduce radiation exposure during X-ray examinations. This PPE is not designed to provide protection from the primary beam, but only from scattered radiation and that transmitted through the patient.

23 Guidance on specific requirements for PPE is given in Reference A.

24 Each piece of X-ray PPE is to have its own identifying number. Gloves and aprons are to be visually examined at 3-monthly intervals and radiographically examined at least every 12 months for the determination of deterioration or reduction in shielding effectiveness. Records of examinations are to be kept for 2 years.

Protection of Patients

25 Radiation doses to patients are to be as low as reasonably practicable in accordance with the intended clinical purpose.

26 Notices are to be displayed requesting female patients to inform radiographers if they suspect or know that they are pregnant.

27 The patient record is to be annotated to confirm that each exposure has been justified/authorised and that evaluation of each radiograph has taken place.

X-ray Equipment Records

28 All units and establishments are to maintain the following records for X-ray equipment:

- An inventory of equipment including the name of manufacturer, model number, serial number or other unique identifier, year of manufacture and year of installation;
- A record of all equipment defects, maintenance and QA tests.

Comforter and Carer

29 Where it is necessary for a patient to be supported during a medical exposure, a record of persons acting as supporters is to be maintained.

30 The supporter is preferably to be an adult relative or friend of the patient and must not be pregnant. The supporter must be adequately protected from exposure to X-rays during the examination.

Reporting Procedures Including Those for Patient Doses Much Greater Than Intended

31 Requirements for the reporting and investigation of radiation accidents, incidents and occurrences are given in Leaflet 14.

32 Reporting procedures for a person undergoing a medical exposure who receives a radiation dose that is much greater than intended as a result of a defect or malfunction in equipment are given at Leaflet 14 Annex G.

33 Reporting procedures for a person undergoing a medical exposure who receives a radiation dose that is much greater than intended as a result of clinical error are equivalent to those given at Leaflet 14 Annex G except that the external body to be notified is the Care Quality Commission (not the Health and Safety Executive).

34 Patient doses deemed to be much greater than intended vary from 1.5 to 20 times the intended dose depending on the type of examination. Details are provided in the department's employer's procedures for patient protection or from the RPA.

This page is intentionally blank

Leaflet 26 Annex B

Content of Employer's Written Procedures for Medical Exposures

1 The written procedures for medical exposures are to be produced to cover the following matters where appropriate:

- To correctly identify individuals to be exposed to ionising radiation;
- To identify individuals entitled to act as referrer, practitioner and operator;
- To be observed in the case of medico legal exposures;
- For making enquiries of women of child bearing age to establish whether the individual is pregnant;
- For the following of quality assurance programmes;
- For the assessment of patient dose;
- For the use of diagnostic reference levels for radiodiagnostic examinations, specifying that these are expected not to be exceeded for standard procedures when good and normal practice regarding diagnostic and technical performance is applied;
- For the use of dose constraints established by the employer for biomedical and medical research programmes where no direct medical benefit for the individual is expected from the exposure;
- For carrying out and recording of an evaluation for each medical exposure including factors relevant to the patient dose;
- To ensure that the probability and magnitude of accidental or unintended doses to patients from radiological practices is reduced so far as reasonably practicable.

2 The following procedures are also to be established:

- For ensuring that all practitioners and operators who are contracted to work in the radiology department are appropriately trained and undertake continuing education and training;
- For keeping records of training for practitioners and operators;
- For the reporting of incidents involving a medical exposure (excluding equipment defect) which has resulted in a patient dose much greater than intended;
- For ensuring that all exposures are justified prior to a medical exposure taking place;
- For ensuring that clinical audit is carried out in accordance with national procedures;
- For providing written protocols for every type of standard radiological practice for each equipment, e.g. an exposure factors chart;

- For providing recommendations concerning referral criteria for medical exposures including radiation doses, and shall ensure that these are available to the referrer.