LEAFLET 25

DENTAL X-RAY MACHINES

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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 describes the requirements for keeping and use of dental X-ray machines. 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 Regulations 1999, the following specific legislation applies:

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

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. TheCO/HoEis 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 dental exposure, the CO/HoE must ensure that such equipment is designed, installed and maintained so far as is reasonably practicable to restrict the exposure of any person undergoing a dental exposure to that which 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.

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) and reporting procedures for incidents are followed. The RPS is normally the practice manager or senior dental officer within the department.

Employees

6 It is the responsibility of all employees to ensure that X-ray equipment is used correctly and not deliberately misused or interfered with. Any incidents are to be reported appropriately (see Leaflet 14).

HAZARD

Table 1 Hazard

Radiation type		Emitted	Comments
Alpha		×	
Beta	Direct	×	
	Bremsstrahlung	×	
Gamma		×	
X-rays		✓	A dose rate of approximately 5 mGy s^{-1} is produced at the end of the collimator on a typical Gendex intraoral machine.
Neutrons		×	

LEGAL AND MOD MANDATORY REQUIREMENTS

Table 2 Legal and MOD Mandatory Requirements

Requirement	Applicable	Comments	Related leaflet*
HSE authorisation	×		
HSE notification	✓		3
EA notification**	×		
Risk assessment	✓		2
Restriction of exposure	✓	Comply with local orders – see Annexes of Leaflet 16. A radiation safety assessment of new and refurbished surgeries and X-ray rooms by the RPA is required.	4, 16
PPE	×	Not normally used.	
Maintenance of radiation engineering controls	✓	For example, power-on warning light, exposure warning light, automatic exposure termination at end of set time and on release of exposure button.	4
Contingency plans	✓	See Leaflet 40.	40
Designated areas	✓	See Annex A of Leaflet 25 and Leaflet 4.	4
Monitoring	×		
Training for users	✓	See Annex A of Leaflet 25 for IRMER training requirements and Leaflet 15 for RPS and user training requirements.	15
Local orders	✓	See Annexes of Leaflet 16 for guidance.	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 IRMER purposes, see Annex A of Leaflet 25.	9
Leak testing	×		
Personal dosimetry	✓	Whole body dosimeters are to be worn by staff routinely involved in radiography procedures.	6
Reporting procedures	✓	See Leaflet 14 and Annex A of Leaflet 26.	14
Transport	×		
Sale/transfer	✓		
Disposal	✓	Return to stores.	
Ionising Radiation (Medical Exposure) Regulations (IRMER) 2000	✓	See Annexes of Leaflet 25.	-

*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).

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LEAFLET 25 ANNEX A

SPECIFIC REQUIREMENTS AND RECOMMENDATIONS FOR DENTAL X-RAY MACHINES

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REFERENCES

A Medical and Dental Guidance Notes, Prepared by Institute of Physics and Engineering in Medicine, 2002.
B Guidance Notes for Dental Practitioners on the Safe Use of X-ray Equipment, British Dental Association et al, 2001.
C Ionising Radiation (Medical Exposure) Regulations 2000.
D Selection Criteria for Dental Radiography, Faculty of General Dental Practitioners (UK) Good Practice Guidelines.
E Defence Dental Service Standard Operating Procedures
F Institute of Physics and Engineering in Medicine (IPEM) Report 91, Recommended Standards for the Routine Performance Testing of Diagnostic X-ray Imaging Systems.

RADIATION SAFETY ASSESSMENT FOR NEW OR REFURBISHED FACILITIES

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

ACCEPTANCE TESTING OF NEW X-RAY EQUIPMENT

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

2.1 Dental X-ray machines are to be designed, constructed and installed in accordance with British Standard 60601. Guidance on design, construction and installation of dental X-ray machines is given in References A and B.

CRITICAL EXAMINATION AND DESIGN OF NEW X-RAY FACILITIES

3 A critical examination including an assessment of the adequacy of room shielding is to be carried out on all new or structurally modified dental X-ray facilities prior to being brought into routine use as advised by the RPA. Guidance on design of dental X-ray facilities is given in References A and B.

CONTROLLED AND SUPERVISED AREAS

4 General requirements relating to controlled and supervised areas are provided in Leaflet 4. For specialist techniques, such as cephalometry, guidance is to be sought from the RPA.

5 A dental surgery or X-ray room need not be demarcated as a controlled area where all of the following conditions apply:

5.1 A single intra-oral dental X-ray equipment or dental pantomograph is the only equipment operated in the examination room at any one time;

5.2 The workload does not exceed in any week 100 single X-ray exposures or 50 panoramic examinations;

5.3 The equipment is of sound construction and properly maintained;

5.4 The operator can see any person within the vicinity of the controlled area defined as:

5.4.1 Within the primary beam until it has been sufficiently attenuated by distance or by absorption, and

5.4.2 Within 2m of the X-ray tube or the patient's head in any other direction, or unless at a lesser distance, the radiation has been adequately absorbed;

5.5 The X-ray equipment can be quickly de-energised from the normal operating position.

6 Radiation warning signs incorporating the radiation trefoil warning symbol and wording 'X-rays' are to be posted on entry doors to dental surgeries and dedicated X-ray rooms containing installed X-ray sets, together with the name and contact number of the RPS.

EXPOSURE PROTOCOLS

7 Where pre-set exposure times are not programmed into the X-ray controller, written protocols must be in place for each type of standard radiological practice for each piece of equipment. This will involve noting the exposure time selected for different intraoral examinations on Secondent-type controllers and, for dental pantomographs, the exposure factors and Automatic Exposure Control (AEC) use as appropriate. These are to be recorded in the form of an exposure chart and signed and dated by the RPS.

7.1 A record of the type of exposure or exposure factors used must be made in each patient's notes.

PRACTITIONERS, OPERATORS AND REFERRERS

8 Reference C requires that each individual dental exposure is justified by an Ionising Radiation (Medical Exposure) Regulations (IRMER) practitioner and any practical aspect, including film processing, associated with the exposure carried out by an IRMER operator.

8.1 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 dental exposure to a practitioner.

8.2 The dental practitioner is normally the IRMER practitioner and may simultaneously fulfil the roles of referrer, practitioner and operator.

TRAINING

9 Adequate training is required for IRMER practitioners and operators.

9.1 In most circumstances, adequate training, as required by Reference C, is given during professional training or a MOD recognised training course, i.e. the DDS Spec Rad course.

9.2 Adequate training comprises appropriate theoretical knowledge of elements as detailed in Schedule 2 of Reference C, together with relevant practical experience, mentoring and continuing professional training.

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

EMPLOYER'S PROCEDURES

10 Reference C requires that there are written standard operating procedures for patient protection for medical exposures. The written procedures are to include the matters set out at Annex B, where appropriate. Procedures for work in DDS dental clinics are provided at Reference E. The regulations also require the employer to ensure that a medical physics expert is involved in medical exposures as appropriate, e.g. measurement and optimisation of patient dose. Guidance on the medical physics expert is given in References A and B, further information may also be obtained from the RPA.

REFERRAL CRITERIA

11 Employers have a duty to define referral criteria for dental exposures, including radiation doses, to all those acting as referrer. Guidance on referral criteria is given at References D and E.

QUALITY ASSURANCE AND PATIENT DOSE ASSESSMENT

12 All units and establishments are to operate a quality assurance (QA) programme for dental X-ray and film processing equipment. The QA programme is to include routine testing carried out by department staff and testing by the RPA every 3 years. Guidance on such testing is given at References E and F.

12.1 Routine testing comprises a radiographic image quality test prior to radiography or on a daily basis and recording reasons for clinical radiographs assessed as less than perfect. It should also include a routine check of the condition of X-ray and film processing equipment.

PROTECTION OF PATIENTS

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

13.1 If the patient is a woman who is or who may be pregnant and where the X-ray beam is directed towards the abdomen a protective apron of at least 0.25mm lead equivalence is to be used to protect the abdomen.

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

X-RAY EQUIPMENT RECORDS

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

14.1 An inventory of equipment including the name of manufacturer, model number, serial number or other unique identifier, year of manufacture and year of installation.

14.2 A record of all equipment defects, maintenance and QA tests.

REPORTING PROCEDURES FOR PATIENT DOSES MUCH GREATER THAN INTENDED

15 General requirements for the reporting and investigation of radiation occurrences are given in Leaflet 14.

15.1 Where as a result of a defect or malfunction in equipment, a person undergoing a medical exposure receives a radiation dose that is much greater than intended, the RSO or RPS is to be informed. Actions are then to be taken in accordance with Leaflet 14 and the RPA informed.

15.2 Where a significant exposure, resulting in a dose much greater than intended, is received by the patient as the result of operator error or equipment malfunction, advice on appropriate action is to be obtained from the RPA. A dose much greater than intended for dental exposure is typically 20 times (or greater) than the intended dose.

LEAFLET 25 ANNEX B

CONTENT OF EMPLOYER'S WRITTEN PROCEDURES FOR DENTAL EXPOSURES

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

1.1 Procedures to correctly identify individuals to be exposed to ionising radiation;

1.2 Procedures to identify individuals entitled to act as referrer, practitioner or operator;

1.3 Procedures to be observed in the case of medico legal exposures;

1.4 Procedures for making enquiries of women of child bearing age to establish whether the individual is pregnant;

1.5 Procedures for the following of quality assurance programmes;

1.6 Procedures for the assessment of patient dose;

1.7 Procedures 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;

1.8 Procedures 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;

1.9 Procedures for carrying out and recording of an evaluation for each medical exposure including factors relevant to the patient dose;

1.10 Procedures 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 Procedures should also be established:

2.1 For ensuring that all practitioners and operators who are contracted to carry out clinical radiography are appropriately trained and undertake continuing education and training;

2.2 For keeping records of training for practitioners and operators;

2.3 For the reporting of all incidents involving a medical exposure (excluding equipment defect) which has resulted in a patient dose much greater than intended;

2.4 For ensuring that all exposures are justified prior to a medical exposure taking place;

2.5 For ensuring that clinical audit is carried out in accordance with national procedures;

2.6 Written protocols for every type of standard radiological practice for each equipment, e.g., providing an exposure factors chart for each equipment;

2.7 Recommendations concerning referral criteria for medical exposures including radiation doses, and shall ensure that these are available to the referrer.

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