Guidance for Dental Clinics:

Complying with Maltese Radiation Protection Regulations
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1 Preface
This document aims to inform dental clinics in how to comply with Maltese radiation protection legislation, and to inform clinics on how to ensure the risks to persons arising from the use of x-rays used is as low as reasonably practicable consistent with the health benefits intended.

These requirements can be met by each clinic having its own Radiation Protection Programme (see annex I for summary of programme).

This guidance combines the requirements of the Nuclear Safety and Radiation Protection Regulations 2003, Legal Notice 44/2003 and the Medical Exposure (Ionising Radiation) Regulations Legal notice, 353/2012.

The sections that follow aim to give dental clinics clear and simple guidance and tasks that need to be performed and whenever possible examples have also been given.

Dental clinics are advised to refer to EUROPEAN COMMISSION, Radiation Protection 136, European guidelines on radiation protection in dental radiology, The safe use of radiographs in dental practice for more detailed information.

2 Roles and Responsibilities within the clinic
Each clinic needs to know who will fulfil the following responsibilities.

2.1 Overall responsibility for radiation safety
The clinic needs to have someone who has the overall responsibility for radiation safety for staff, patients and the general public. This person could be the clinic owner.

2.2 Radiation Protection Supervisors
The clinic needs to appoint one or more Radiation Protection Supervisors to supervise that the clinic radiation safety rules (Local Rules) are being complied with.

2.3 Qualified Experts/ Medical Physics Experts
Qualified Experts/ Medical Physics Experts may need to be consulted for radiation protection advice.
3 Roles and Responsibilities under the Medical Exposure Regulations

Under the Medical Exposure regulations each clinic needs to know and document who will act as prescribers, practitioners and the persons performing the practical aspects. It is allowed and quite likely that a dentist may perform some or all of these roles.

3.1 Employers

The employer (including dentist who owns a practice) shall ensure that written procedures for medical exposures are in place and shall include:

(1) procedures to identify correctly the individual to be exposed to ionising radiation;
(2) procedures to identify individuals entitled to act as prescribers and, or practitioners, and persons performing the practical aspects;
(3) procedures to be observed in the case of medico/legal exposures;
(4) procedures for making enquiries of females of childbearing age to establish whether the individual is or may be pregnant or breastfeeding;
(5) procedures to ensure that quality assurance
(6) procedures for the assessment of patient dose and administered activity;
(7) procedures for the use of diagnostic reference levels;
(8) procedures for medical and biomedical research programmes as referred to in regulation 4(1)(d), including the use of dose constraints;
(9) procedures for the giving of information and written instructions as referred to in regulation 20;
(10) procedures for the carrying out and recording of doses for each medical exposure including, where appropriate, factors relevant to patient dose;
(11) procedures to ensure that the probability and magnitude of accidental or unintended doses to patients from radiological practices are reduced as far as reasonably achievable;
(12) procedures for the carrying out of clinical audit as appropriate.

3.2 Prescribers

A Prescriber must be a registered medical doctor or a dentist.

Functions of a Prescriber are:

(1) Ensure and document that the medical exposure of the patient is warranted based on the medical indications
(2) Make reference to referral criteria
(3) Refer the patient to a practitioner, providing adequate clinical details. Stating on each individual referral the clinical question to be answered
(4) Where practical, seek, to obtain previous diagnostic information or medical records relevant to the planned exposure and consider this data to avoid unnecessary exposure.

(5) Seek the outcome of the exposure and act on the result

3.3 Practitioners

A Practitioner shall normally be a qualified dental surgeon or registered radiographer.

Functions of a Practitioner are:

(1) Select equipment and methods to ensure that for each medical exposure the dose of ionising radiation to the individual undergoing the exposure is as low as reasonably achievable and consistent with the intended diagnostic purpose and in doing so shall pay special attention to.

(a) quality assurance, and

(b) assessment of patient dose, and

(c) use of diagnostic reference levels

(2) The practitioner shall sanction medical exposures.

(3) The practitioner shall take clinical responsibility for medical exposure.

(4) The practitioner shall make arrangements to satisfy himself that the individual medical exposure as prescribed is justified, by ensuring that there is sufficient net benefit by this exposure for the patient, the benefit to comforters and carers against the detriment that the exposure might cause. This should be based on his knowledge of the hazard associated with the exposure and the clinical information supplied by the prescriber.

(5) The practitioner where practical, shall seek, to obtain previous diagnostic information or medical records relevant to the planned exposure and consider this data to avoid unnecessary exposure.

3.4 Persons performing the practical aspects

These persons need the following experience:

First time registered radiographers, Practitioners, excluding dentists, shall have at least one month on the job training under the supervision of an approved individual in the specific area.

No initial experience for dental work performed by dental surgeons specific area

The physical conduct of any of the exposures may be delegated by the employer or the practitioner, as appropriate, to one or more individuals authorized by the Superintendent of Public Health to act in this respect.
4 New Clinic being set up or new x-ray equipment being installed

Before a new clinic/or new x-ray equipment is installed:

- The clinic must inform the RPB 30 days beforehand.
- No new x-ray equipment should be installed into a Clinic before consulting with a Qualified Expert (QE) / Medical Physics Expert (MPE) who can advise on legislative compliance and safety.

5 Clinic layout and signage.

5.1 Plan of Clinic

There should be a simple plan giving room layout and location of x-ray equipment and information on room shielding.

5.2 Radiation Shielding

Before embarking on the installation of any shielding to walls or doors it is recommended that a Qualified Expert is consulted. Often additional shielding is not required for rooms housing intra-oral equipment but is often required for panoramic type equipment.
5.3 Radiation Warning Signs

There should be a sign at each entrance door to each room where x-rays are taken. The sign should contain the radiation trefoil sign, the wording: Controlled Area (or Supervised Area) and the wording: X-rays. A clinic may opt to have a light box type signage but this is not a requirement under Maltese regulations.

EXAMPLE

X-RAY HAZARD
CONTROLLED AREA

DO NOT ENTER UNLESS AUTHORISED

6 X-ray equipment

6.1 Inventory

The clinic needs to have a written inventory of its x-ray equipment.

For each piece of equipment the basic information as shown in the below example should be available:

EXAMPLE

<table>
<thead>
<tr>
<th>Intra-oral /panoramic/cephalometric/CT</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Model Number</td>
</tr>
<tr>
<td>Serial number or other unique identifier</td>
<td>Year of manufacture</td>
</tr>
<tr>
<td></td>
<td>Year of Installation</td>
</tr>
<tr>
<td></td>
<td>Date of Acceptance test</td>
</tr>
<tr>
<td></td>
<td>Maximum kV</td>
</tr>
<tr>
<td></td>
<td>Location in clinic</td>
</tr>
</tbody>
</table>

EXAMPLE
6.2 Acceptance testing
To be done on installation and any existing equipment that has not gone through an acceptance test must have done one by 19th April 2013.

Acceptance test to be kept for the life-time of the equipment.

The RPB does not specify who should perform these tests but rather that they should be done against a standard

6.3 Constancy test
To be done at least every two years

To be kept for three years

7 Staffing Approval and training records

7.1 Approval
The clinic needs to maintain a list of Staff and their responsibilities with regard to anything to do with the medical exposure of patients from x-rays.

The clinic needs to approve persons to perform activities related to the medical exposure of patients.

Holding a written list of staff will major part of the approval process

7.2 Training
Training that the above staff have received, should be documented.
7.3 Example of Approval and Training Records

<table>
<thead>
<tr>
<th>Name</th>
<th>Approved to:</th>
<th>Radiation Protection Training</th>
</tr>
</thead>
</table>
| Dr Filfla    | To Prescribe, Take and interpret intra-oral and panoramic radiographs | Initial dental course at UoM in 1999  
Specialised training at the University of Sussex 2004 |
| Dr Rock      | To Take intra-oral and panoramic radiographs | Initial dental course at UoM in 1999               |

8 Radiological Risk Assessment

There needs to be a written risk assessment, this would have been done at the time of the initial notification to the RPB and should be reviewed as required, below find sample risk Assessment form.

A dental radiological risk assessment is nothing more than a careful examination of how staff, patients and the general public could be exposed to dental x-rays and the precautions taken to minimize the risk.

The aim of the following questions is to enable the first written estimate of risk to be made.

Advice from a Qualified Expert can be sought in connection with completing a Risk Assessment.
**Risk assessment for radiological hazards from dental x-ray equipment:**

Please include any additional information relevant to the risk assessment on a separate sheet.

**8.1 Staff**

Does any member of staff remain in the same room in which the radiograph is being taken? Yes/No

At what distance do staff stand away from the patient when radiograph is taken if he remains in the room?

Do staff stand behind any shielding material when the radiograph is taken eg a solid wall, lead apron? Please give details.

**8.2 Patients**

Are previous radiographs/records available to prevent unnecessary repeat radiographs? Yes/No

What protective devices are available for the patient to use, give details.

Who enquires about the possibility of patient pregnancy?

What additional precautions, if any are taken when a radiograph of a woman who might be pregnant are taken?

What special precautions are taken when taking radiographs of children?

Is the child held in position during the radiograph? If so by who?

**8.3 General Public**

What steps are taken to ensure that the x-ray equipment cannot be switched on by a member of the general public?

Are the General Public in the same room as the patient during a radiographic technique? Yes/No
9 Local Rules

For the operation of the equipment there needs to be a set of local rules. Issues to consider in the local rules include.

Advice from a Qualified Expert can be sought in connection with completing a Risk Assessment

EXAMPLE

The Radiation Protection Supervisor for the clinic is Dr XXXX

9.1 Protection of Staff

If staff need to remain in room they shall be at least 2 Metre from intra-oral. 
Staff taking intra oral to stand________
Staff not to remain in same room as OPG

9.2 Protection of Patients

Previous radiographs/records must to be referred to before taking any new radiograph.

Each Radiographic image is to be stored along with the patient records.

The following protective devices are available are to be used for the patient to use __________

Dr __________ is responsible for enquiring about the possibility of patient pregnancy

If a patient is pregnant the policy of the clinic is to________________

What additional precautions, if any are taken when a radiograph of a women who might be pregnant are taken.

The following precautions are taken when taking radiographs of children
Is the child held in position during the radiograph? If so by who?

9.3 Protection of General Public

The following steps are taken to ensure that the x-ray equipment cannot be switched on by a member of the general public?

General Public are not allowed room as the patient during a radiographic technique
10 Patient Image management and Patient Dose Assessment

10.1 Dose per procedure
The clinic needs to know what the radiation dose per procedure is and appropriate staff need to be aware of this document

10.2 Diagnostic Reference Levels
How do these doses compare to Diagnostic reference levels

If the clinic knows what the absorbed dose in air measured at the end of the spacer cone for a standard maxillary molar projection it can compare it to the value recommended value of 4mGy given as recommendation 5f of RP136

<table>
<thead>
<tr>
<th>Exam</th>
<th>Patient Entrance Dose/Dose Area Product</th>
<th>Effective Dose Entrance Dose/Dose Area Product (RP136)</th>
<th>UK 2010 review</th>
</tr>
</thead>
</table>
10.3 Justification and the use of Referral Criteria

It is recommended that section 3 of EUROPEAN COMMISSION, Radiation Protection 136, European guidelines on radiation protection in dental radiology, The safe use of radiographs in dental practice is referred to.

All X-ray examinations must be justified on an individual patient basis by demonstrating that the benefits to the patient outweigh the potential detriment. The anticipated benefits are that the X-ray examination would add new information to aid the patient’s management.

No radiographs should be selected unless a history and clinical examination have been performed. ‘Routine’ radiography is unacceptable practice.

When referring a patient for a radiographic examination, the dentist should supply sufficient clinical information (based upon a history and clinical examination) to allow the practitioner taking clinical responsibility for the X-ray exposure to perform the justification process.

Access to previous radiographs will avoid unnecessary exposures and aid patient management.

11 Annexes

11.1 Annex I - Radiation Protection Programme Contents summary:

Recommended Minimum include–

1. Sketch of clinic
2. Equipment inventory
3. Acceptance tests for each x-ray equipment
4. Constancy tests for each x-ray equipment
5. Radiological Risk Assessment
6. Local Rules
7. Staff Training Records
8. Clinic approval records of its staff
9. Records of Patient exposures (including exposure parameters)
10. Table of dose per procedure/diagnostic reference levels
11. Referral criteria and Justification practises
12. Procedure to identify correctly the individual to be exposed to ionising radiation
13. Procedure to identify individuals entitled to act as prescribers and/or practitioners, and persons performing the practical aspects?
14. Procedure enquiries of females of childbearing age to establish whether the individual is or may be pregnant?
15. Procedure to ensure that quality assurance programmes are followed
11.2 Annex II - References/Further reading

Nuclear Safety and Radiation Protection Regulations 2003, Legal Notice 44/2003

Medical Exposure (Ionising Radiation) Regulations Legal notice, 353/2012.


Guidance Document for Medical Exposure (the ionising radiation) regulations, 2012 LN 353/2012

EUROPEAN COMMISSION, Radiation Protection 136, European guidelines on radiation protection in dental radiology, The safe use of radiographs in dental practice

Radiation Exposure of the UK Population from Medical and Dental X-ray Examinations
http://www.medicalphysicist.co.uk/nrpw4.pdf