

**GUIDELINES ON
RADIATION SAFETY
IN DENTISTRY**

APPENDIX 1

Statutory Authorities

Where advice or assistance is required from the relevant statutory authority, it may be obtained from the following authorities:

1. Director
Engineering Services Division
Ministry of Health
Aras 2-5, Blok E6, Parcel E
Pusat Pentadbiran Kerajaan Persekutuan
62590 Putrajaya
MALAYSIA
Tel: 03-8883 3888 Fax: 03-8888 6184
2. Lembaga Perlesenan Tenaga Atom
Kementerian Sains, Teknologi dan Alam Sekitar,
Batu 24, Jalan Dengkil, 43800 Mukim Dengkil,
Sepang, Selangor
Tel: 03-8926 7699 Fax: 03-892 23685

GUIDELINES ON RADIATION SAFETY IN DENTISTRY

1st Edition

10. European Commission. European Guidelines on Radiation Protection In Dental Radiology. The Safe Use of Radiographs In Dental Practice. Luxembourg: 2004, Radiation Protection 136
11. National Radiological Protection Board UK. Guidance Notes for Dental Practitioners on the Safe Use of X-Ray Equipment. NRPB dental x-ray protection services 2001
12. Health Canada, 2000. Recommended Safety Procedures for the Use of Dental X-Ray Equipment. Radiation Protection in Dentistry. Safety Code 30
13. Australian Government. Code of Practice and Safety Guide. Radiation Protection in Dentistry. Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) 2005. Radiation Protection Series Publication No. 10
14. Law of Malaysia Act 586 -Private Healthcare Facilities and Services (Private Medical Clinics or Private Dental Clinics) Regulations 2006

**Oral Health Division
Ministry of Health Malaysia
July 2006**

8. References

1. Ministry of Science, Technology and Innovation, Malaysia. Malaysian Institute for Nuclear Technology Research Radiation Awareness. 1st ed., pp 13-23. 2005
2. Abbott P. Are Dental Radiograph Safe?. Aust Dent J 2000 ;45:(3):208-213
3. Laws of Malaysia Act 304 - Atomic Energy Licensing Act 1984
4. Atomic Energy Licensing Act 1984 - Radiation Protection (Basic Safety Standards) Regulation 1988
5. Atomic Energy Licensing Act 1984 - Radiation Protection (Licensing) Regulations 1988
6. Ministry Of Health Malaysia. Guidelines to Obtain Class C Licence Under The Atomic Energy Licensing Act (Act 304), 2000
7. Ministry of Health Malaysia. Circular on additional requirements that need to be complied with entitled Licensing Requirements Under The Atomic Energy Licensing Act 1984 (Act 304) For Specialised Diagnostic Radiology Services Provided By Private Hospitals/ Radiology Clinics No (5)d/m.KKM 153(13/172)Bhg2 (MOH, 1999)
8. Standards and Industrial Research Institute of Malaysia (SIRIM) Malaysian Standards (MS 838) - Code Of Practice For Radiation Protection (Medical X-ray Diagnosis), 1985
9. Malaysian Dental Council. Code of Professional Conduct. Pg 14. 1997

Advantage of Using Fast Speed Film

"A study done by The Nationwide Evaluation of X-ray Trends (NEXT) United States in 1999 showed that, the amount of radiation a person is typically subjected to for D-speed film was 1.7 milligray (mGy) (a unit of radiation exposure) per film, and 1.3 mGy for E-speed film. These results show a 23% reduction in exposure with the use of E-speed film over D-speed film."

<http://www.fda.gov/cdrh/radh11h/dentalradio.html>

FOREWORD BY THE DIRECTOR FOR ORAL HEALTH MINISTRY OF HEALTH MALAYSIA

The safe and effective use of dental x-ray equipment is important for the protection of the patient, public and dental personnel. Thus far, there are about 414 dental x-ray machines available in government dental clinics throughout Malaysia. These dental x-ray machines range from intra-oral, panoramic and cephalometric radiographic equipment.

Although the radiation dose of an average dental radiological examination is low, repeated dosage may be a potential hazard. Exposure can be minimized through meticulous adherence to good practice. It is timely that the Oral Health Division take initiatives to ensure that the dental personnel understand, practice and internalize the precautionary measures to protect themselves and their patients from unnecessary ionizing radiation. This document is to assist dental practitioners to comply with requirements on radiation safety, which include monitoring performance of x-ray machines and implementing quality assurance (QA) activities.

I would like to take this opportunity to thank all the personnel involved in the preparation of this document

DATO' DR WAN MOHAMAD NASIR BIN WAN OTHMAN
Director of Oral Health
Ministry of Health Malaysia

7. Conclusion

Even though the radiation dose in dental radiography is very low, it is important for the dental practitioners to follow these guidelines to ensure all dental personnel, patients and public are protected from unnecessary ionising radiation. Dental practitioners should not be complacent about the low risks of dental radiography. They are professionally responsible to use radiography appropriately in their practices and to maintain good, safe radiation procedures at all times.

WORKING GROUP

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- Radiation Protection and Safety in Healthcare Unit, Engineering Services Division, Ministry of Health Malaysia
- The Oral Health Division, Ministry of Health Malaysia
- All those who had provide precious contribution and comment

patient's clinical records in one clinic should detail all radiographic examinations carried out.

4. Repeat radiographic examination should not be prescribed just because a radiogram is not at its 'best' diagnostic quality. Often, the information may provide the required clinical information without having to repeat the investigation.
5. It should be emphasized that precautions to minimize radiation exposure should be taken all the time for women of child-bearing age as a woman may be unaware of her pregnancy status.
6. The patient must be provided with a lead apron at all times for gonad protection. The use of a thyroid shield for children is especially important especially during occlusal radiographic examination.
7. The patient's head should be positioned in such a way that the primary beam is not directed at the gonads and is not unnecessarily irradiating the patient's body.
8. A fast speed film (speed group E or faster) as classified by International Organization for Standardization (ISO) should be used.

8. Where there is a need to support children or weak patients, holding devices should be used. If parents, escorts or personnel are called to assist, they must be provided with protective clothing/aprons and be positioned to avoid the primary beam. No one must regularly perform these duties.
9. All x-ray tube housing must not be held by hand during operation.

6. Procedures To Minimise Radiation Exposure To Patients

It is the responsibility of the operator and dental practitioner to carry out a prescribed examination with the lowest practical dose to the patient. A summary of the essential procedures are listed below.

1. Every effort must be made to avoid unnecessary radiological examination and when required, it is essential that patients be protected from excessive radiation exposure during examination.
2. A radiographic examination should be for the purpose of obtaining diagnostic information about the patient's conditions. Routine or screening examination without prior clinical assessment should not be prescribed.
3. It should be determined whether there have been previous radiographic examinations which might make further investigations unnecessary. Where practicable, a

Contents	Page
<i>Foreword</i>	i
<i>Working group</i>	ii
1. Introduction	1
2. Objectives of the Guidelines	1
3. Responsibilities	2
3.1 Ensuring that the Dental Radiation Equipment Comply With the Regulatory Requirements	3
3.2 Establishing Safe Working Area	6
3.3 Ensuring Safe Work Procedures	7
3.4 Ensuring the Equipment Function Properly and are Well Maintained	9
3.5 Ensuring that Operators are Properly Trained to Operate the Equipment and to Undertake Proper Procedures	11
4. Quality Assurance	10
4.1 Establishing Equipment Performance / Operation	12
4.2 Ensuring Proper Film Storage	13
4.3 Establishing Administrative Procedures	13
5. Procedures To Minimise Radiation Exposure To Personnel	14
6. Procedures To Minimise Radiation Exposure To Patients	15
7. Conclusion	17
8. References	18
9. Appendix 1	20

1. Introduction

Dental radiography is a valuable diagnostic tool in modern dental practice and its judicious use allows dental practitioners to diagnose and monitor physical conditions that would otherwise be difficult to identify. However, the use of dental radiological procedures must be carefully managed as any type of x-radiation has the potential to damage healthy cells and tissues.¹ Although the radiation dose received by an individual is low during an average dental radiological examination, repeated low dosages over time may accumulate and could present a potential health hazard. To date, there has been no known occurrence of malignant or genetic changes due to dental radiography.² Nevertheless, it is incumbent upon all members of the dental profession to exercise vigilance and to undertake precautionary measures to ensure health and safety of personnel, patients and the public.

2. Objectives of the Guidelines

These guidelines apply to the use of equipment designed for radiography of the teeth or jaws including the use of an intra-oral image receptor, panoramic and cephalometric radiography. It is prepared to assist dental practitioners to comply with requirements on radiation safety.

The relevant authorities that are responsible for ensuring compliance to the Act and regulations on radiation safety are listed in Appendix 1.

5. Procedures To Minimise Radiation Exposure To Personnel

The procedures below summarises the steps to be undertaken in order to keep radiation exposures to personnel and others to a minimum.

1. Dental radiographic equipment must only be operated by personnel trained in its safe use.
2. The controlled area must not be used at the same time for more than one radiological investigation.
3. All persons, except for the patient and those whose presence are required, must leave the room when a radiographic examination is in progress.
4. Personnel must keep as far away from the primary radiation beam as possible.
5. All personnel must use the protective devices available.
6. The operation of the x-ray equipment should be controlled from outside the controlled area or behind a protective screen.
7. The dental film should be kept in position with a holding device whenever possible. If unavailable the film should be held in place by the patient himself/herself. The dental personnel must not hold the film in place for the patient during the procedure.

4.2 Ensuring Proper Film Storage

Unexposed x-ray films shall be stored in a container adequately shielded against radiation or in an area remote from any x-ray unit and away from excessive heat, humidity or chemical contamination.¹³

4.3 Establishing Administrative Procedures

Keeping records

An up-to-date inventory of each item of x-ray equipment is important, and shall be available at each practice and shall contain the following:

- Name of manufacturer
- Model number
- Serial number
- Year of manufacture
- Year of installation
- Maintenance records

The specific objectives are to:

- minimise radiation risk to the patient;
- ensure adequate protection of dental personnel operating dental radiation equipment; and
- ensure adequate protection of members of the public near areas where such equipment is operated.

To assist dental practitioners and auxiliaries to achieve these objectives, this guideline:

- lists the responsibilities of the dental practitioner;
- specify minimum standards for physical facilities in which dental radiation equipment is operated;
- present recommended practices to minimise radiation risk to personnel and patients, which include ensuring proper and safe use of dental radiation equipment; and
- recommends quality assurance procedures for dental radiation safety.

3. Responsibilities

The dental practitioner is ultimately responsible for radiation safety within the dental facility. Handling of the equipment, however, may be delegated to other personnel who are trained to undertake such procedures.

The responsibilities of the dental practitioner cover the following:

- ensuring the dental radiation equipment comply with the regulatory requirements;
- establishing safe working area;

- establishing safe work procedures;
- ensuring the equipment functions properly, and is maintained regularly; and

- ensuring that operators are properly trained to operate the equipment and to undertake proper procedures.

3.1 Ensuring that the dental radiation equipment comply with the necessary requirements

3.1.1 Legislation- The Atomic Energy Licensing Act 1984 (Act 304)

The Atomic Energy Licensing Act 1984 (Act 304) is an act to provide for the regulation and control of atomic energy, for the establishment of standards on liability for nuclear damage and for matters connected or related to it.³

Under the provision of section 12(1)(b), Atomic Energy Licensing Act 1984 (Act 304), no person shall deal in, possess or dispose of any radioactive material, nuclear material, prescribed substance or irradiating apparatus, unless he is the holder of a valid licence issued under section 16(5) by the appropriate authority for such purpose and as specified in the licence.

3.1.2 Regulations

There are three regulations under this Act namely :

- the Radiation Protection (Licensing) Regulations 1986;⁴ and
- the Radiation Protection (Basic Safety Standards) Regulations 1988.⁵

- iii. Professional education on use of x-ray equipment, hazard of ionising radiation and radiation safety.

4.1 Establishing Equipment Performance / Operation

Quality control procedures include ensuring the dental x-ray equipment, protective devices and film processing equipment function properly and adequately.⁷ This includes replacement, repair, upgrading and calibration of equipment, where necessary. Technical evaluation should include the following:

Dental x-ray equipment

- Calibration of equipment
- Proper radiation beam alignment
- Mechanical and electrical performance
- Inspection and replacement of worn or broken components
- Following the manufacturer's preventive maintenance schedule.

Protective Devices

- Inspection of protective devices including lead shields, aprons and thyroid shield.

Films processing equipment

- Inspection of storage tanks, condition of processing equipment and maintenance schedule.

3.5.2 Staff Welfare

A female operator should notify the dental practitioner upon knowledge that she is pregnant, in case appropriate steps need to be taken to adjust her duties. However, in general, there is no reason to remove pregnant operators from their duties of operating dental radiological equipment provided all protective measures are adhered to.¹²

4. Quality Assurance

The purpose of Quality Assurance is to ensure consistently adequate diagnostic information, whilst radiation doses are controlled to be As Low As Reasonably Achievable – the ALARA principle. It is thus essential that dental practitioners observe the basic principles of radiation protection that is, maximize the distance from the source, minimize time of exposure and shield the radiation source. This implies that no dose should be acceptable if it can be avoided or is without benefit.^{7,10}

The essential procedures within a programme suited to dental radiology will relate to:

- i. Quality control (QC) of equipment operation and baseline performance of radiographic equipment;
- ii. Image quality – monitoring and analysis of film reject rate. The corrective action should be taken if the reject rate is more than 10%; and

- Radiation Protection (Transport) Regulations 1989.

Under the provision of regulation 6(1) of the Radiation Protection 1986 Regulations, Class C licence is defined as a licence to manufacture, trade in, produce, process, purchase, own, possess, use, transfer, handle, sell or store irradiating apparatus.

The Radiation Protection (Basic Safety Standards) Regulations 1988 shall apply to all activities involving ionizing radiation. Regulation (18) says that dental practitioners shall ascertain whether the radiography is necessary before any exposure is administered to the patient. Whereas, regulation (24) and (25) denote the responsibilities of dental officers to monitor radiography work areas.

3.1.3 Guideline and Circular

The Ministry of Health Malaysia has produced documents to provide assistance in complying to the Act. The documents encompass:

- Guidelines on the procedure for application of a Class C licence (MOH, 1995) - Guideline to Obtain Class C Licence, Under Atomic and Energy Licensing Act 1984 (Act 304).⁶

An application for a new licence with processing fee of RM15.00 shall be made using the application form (*Borang LPTA/BP/3*) which can be obtained from the following address:

*Ketua Pengarah,
Ibu Pejabat Lembaga Perlesenan Tenaga Atom (LPTA),
Kementerian Sains, Teknologi dan Alam Sekitar,
Batu 24, Jalan Dengkil, 43800 Dengkil,
Selangor Darul Ehsan.*

LPTA shall then forward the application to the Director General of Health Malaysia for the purpose of licensing. If all requirements are fulfilled, the applicant shall be required to pay a licence fee of RM 100.00 for the first apparatus and RM 50.00 for every additional apparatus. The payment of the licence fee shall be made payable to the Ministry of Health Malaysia. This licence need to be renewed yearly.

3.1.4 Legislation - Private Healthcare Facilities and Services (Private Medical Clinics or Private Dental Clinics) Regulations 2006

The special requirement for location and facilities of the diagnostic imaging services are outlined in Part XIII under regulation 93(1) to regulation 99(3) of this Regulations.¹³ Dental practitioners are advised to ensure that they comply with the requirements as stated in the regulations.

3.1.5 Equipment Requirements

All dental x-ray equipment shall fulfill the requirements stated in the Malaysian Standards (MS 838) Code of Practice for Radiation Protection (Medical X-ray Diagnosis).⁸

Intra-oral films of ISO speed group E, or faster, are preferred as they significantly reduce the amount of radiation by approximately 50%.¹³

Where automatic processing is used, the processor should be properly cleaned and maintained. In the case of manual processing, maintenance should be done in accordance with the manufacturer's instructions.

In order to extract full diagnostic information from the films a specially designed light-box should be used where the ambient lighting can be adjusted to appropriate levels.

3.5 Ensuring that Operators are Properly Trained to Operate the Equipment and to Undertake Proper Procedures

3.5.1 Training of operators

Person who operates the x-ray equipment shall be a dental practitioner or a trained personnel approved by licensing authority⁶. All operators must:

- understand the requirements and recommendations of these guidelines;
- recognize the radiation hazards associated with their work and take measures to minimize them;
- have an understanding of safe working methods and appropriate techniques and procedures; and
- eliminate unnecessary radiographic procedures.

3.3.6 Female Patient of Child-bearing Age

The dental practitioner or personnel undertaking dental radiography shall always enquire into the pregnancy status of any female patient of child-bearing age.^{10,11}

The dental practitioner shall always pay attention to details of radiological techniques that would ensure minimum exposure to any embryo or foetus that might be present, whether or not the women is known to be pregnant.⁵

3.4 Ensuring the Equipment Function Properly and are Well Maintained

3.4.1 Maintenance and Testing

Maintenance and associated checks for intra-oral x-ray shall be done once for every two years and for an OPG yearly, in accordance with the Guidelines to obtain Class C licence from the Ministry of Health. The summary of performance and safety test of the apparatus can be completed and duly signed by an accredited Class H Consultant (medical physicist). An accredited Class H consultant shall possess Class H (certification) licence issued by the Director General of Health Malaysia.⁶

3.4.2 Image Receptor, Processor and Viewer

For intra-oral radiography, the fastest available films consistent with satisfactory diagnostic results should be used.

According to the Code of Professional Conduct issued by the Malaysian Dental Council (1997), all dental practitioners who store and operate machines for purposes of dental radiography and imaging shall abide by the Atomic Energy Licensing Act 1984, and any other such legislation governing the same.⁹

3.2 Establishing Safe Working area

3.2.1 Dimensions of X-Ray Room / Area

Ideally, dental radiography should be undertaken in an x-ray room or a radiography area. This may be a dental surgery, or an examination room, where the room / area is not used for other work while dental radiography procedures are conducted. The required internal dimensions of the room are:

- 2.0 meters (length) by 3.0 meters (width) and 3.0 meters (height) for intra-oral dental x-ray; and
- 2.5 meters (length) by 3.5 meters (width) by 3.0 meter (height) for orthopantograms (OPG) x-ray.⁶

3.2.2 Structural Shielding

For dental radiography, the required thickness of shielding at doors and walls is :

- 1.0 mm lead equivalence (Pb eq) for intra-oral dental x-ray, and
- 1.5 mm Pb eq for x-ray OPG.^{6,12}

3.2.3 Signs and Warning Lights

A basic warning notice and ionizing radiation symbol should be provided on entrance door to any x-ray room / area. Additionally, an automatic warning light, which lights up when radiography is in progress, should be provided outside the room.¹⁰

3.2.4 Use of Protective Screens/Aprons

For radiographic in a small room or area, extra protection should be provided. The use of protective panels with glass (1mm Pb eq) for staff to stand behind, or a protective apron for staff to wear is recommended.^{8;10}

3.3 Ensuring Safe Work Procedures

3.3.1 Written Procedures

Written instructions should be made available and displayed near the x-ray equipment to ensure that personnel are fully aware of the precautions to be taken. These instructions should detail the responsibility of identified personnel for exposure, positioning of operator and patient / public, use of protective devices, any restriction(s) on primary beam direction and personal monitoring arrangements, if appropriate.¹⁰

3.3.2 Use of Protective Clothing

Protective aprons with a lead equivalence of not less than

0.25 mm Pb eq, should be provided for any adult who provides assistance by supporting a patient.

When a lead apron is provided, it must be correctly stored, for example, over a suitable hanger, and not folded. Its condition must be routinely checked, including a visual inspection at annual intervals.^{8;13} Thyroid collars should be used in those few cases where the thyroid may be in the primary beam.

3.3.3 Procedures Specific to Intra-Oral Radiography

Whenever practicable, techniques using film holders incorporating beam-aiming devices should be adopted for bitewings and periapical radiography. If rectangular collimation is being used, a beam-aiming device is essential for accurate alignment with the intra-oral film.¹³

3.3.4 Personal Radiation-Monitoring Devices

It is recommended that personnel operating or assisting in the operation of x-ray systems should be provided with monitoring devices such as a film badge dosimeter or thermo-luminescent detector badge if only the personnel are likely to be exposed to a radiation dose exceeding 1 mSv in any one-year or the equivalent of a weekly workload that exceeds 100 intra-oral or 50 panoramic films.^{10;11}

3.3.5 Patient Positioning

The patient's head and the primary beam should be aligned such that the primary beam is not directed at the patient's gonads and body.¹²