



# Radiation Protection in Dentistry

Safety Procedures for the Installation,  
Use and Control of Dental X-ray Equipment

*Safety Code 30 (2022)*



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## Overview

Safety Codes are a series of documents prepared by Health Canada to provide radiation protection guidance. They help promote consistency in radiation protection practices to support the safe use of radiation emitting devices in Canada.

This document supersedes the previous version of Safety Code 30, entitled “Radiation Protection in Dentistry: Recommended Safety Procedures for the Use of Dental X-ray Equipment,” which was published in 1999. The updates in this version address new dental X-ray technologies, such as hand-held devices, cone beam computed tomography and the introduction of digital image receptors replacing the use of film. These technological advancements, along with new international guidance and standards applicable to dental radiography, necessitate updates to radiation protection requirements and practices.

Safety Codes provide radiation protection guidance, information and advice. Health Canada’s Safety Codes are sometimes referenced in regulations, standards and policies of other authorities, such as federal, provincial or territorial government departments and agencies. In those situations, the applicable department or regulatory authority determines how compliance with the Safety Code is verified. For example, Safety Code 30 is referenced in the *Canada Occupational Health and Safety Regulations* for the instruction and guidance of persons employed in Federal Public Service departments and agencies, as well as those whose employers are under the jurisdiction of the *Canada Labour Code*.

Rules governing the safe installation and use of X-ray equipment, as well as protocols and safety requirements for operators, may be established through provincial and territorial legislation, professional orders and associations. This may include requirements relating to who can perform specific actions or fulfill the roles and responsibilities outlined in this Safety Code. In some cases, provincial/territorial authorities may also reference Health Canada Safety Codes. The authorities listed in Appendix I should be contacted for details of the regulatory requirements of individual provinces and territories and to determine the applicability of this Safety Code.

## Who this Safety Code is For

The information in this Safety Code has been prepared to provide guidance to the owners of dental facilities, dentists, dental hygienists, dental therapists, dental assistants, radiation/X-ray safety officers and other individuals or organizations concerned with radiation safety procedures, equipment performance, and radiation protection for the use of dental X-ray equipment.

## Principle Objectives of this Safety Code

This Safety Code sets out principles and best practices to help ensure radiation protection of all individuals who may be exposed to radiation from dental X-ray equipment. It provides dental facilities with the necessary information to achieve the following principal objectives:

1. to minimize patient exposure to ionizing radiation in dental radiography, while ensuring the necessary diagnostic information is obtained;
2. to help ensure optimal protection of personnel operating dental X-ray equipment; and
3. to help ensure optimal protection of other personnel and the general public in the vicinity of areas where dental X-ray equipment is operated.

To assist in meeting these objectives, this Safety Code:

- A. sets out the qualifications and responsibilities of the owner, the coordinator of the radiation protection program, the X-ray equipment operator, the prescribing dental practitioner, the expert in radiation protection, and repair and maintenance personnel;
- B. presents practices and procedures for minimizing radiation doses from X-ray equipment to operators and the public;
- C. presents practices and procedures to minimize radiation doses to patients while maintaining adequate diagnostic image quality;
- D. presents practices and procedures for ensuring the X-ray equipment is used in a safe manner;
- E. provides information on facility design and shielding requirements;
- F. specifies minimum standards of construction and performance for dental X-ray equipment;
- G. provides information required to implement and operate a quality assurance program for the facility;
- H. provides a list of acceptance tests and quality control tests for various types of dental X-ray equipment and their accessories; and
- I. provides a schedule for performing quality control tests.

## Scope and Limitations

This Safety Code provides radiation protection guidance for the safe installation and use of conventional and hand-held intra-oral dental X-ray equipment, as well as panoramic, cephalometric and conebeam computed tomography extra-oral dental X-ray equipment. It

supersedes the previous version of Safety Code 30, entitled “Radiation Protection in Dentistry: Recommended Safety Procedures for the Use of Dental X-ray Equipment,” which was published in 1999.

The words *must* and *should* in this Safety Code have been chosen with purpose. The word *must* is used to indicate essential radiation protection requirements, while *should* indicates an advisory recommendation that is highly desirable and is to be implemented where possible.

As technology continues to advance, it should be noted that this Safety Code cannot cover all possible situations. Over time, it will be reviewed and revised, and a particular requirement may be reconsidered at any time if it becomes necessary to address unforeseen situations.

Recommendations may be modified in atypical circumstances, but only upon the advice of the relevant authorities and/or experts in radiation protection or dental radiography quality assurance. Interpretation or elaboration on any point can be obtained by contacting the Consumer and Clinical Radiation Protection Bureau, Health Canada (Appendix I).

This Safety Code does not address other aspects of health and safety applicable to dental radiography (e.g. infection control practices).

## In This Safety Code

This Safety Code is composed of three sections: Responsibilities and Protection, Facility and Equipment Requirements and Quality Assurance Program.

### Section A: Responsibilities and Protection

This section sets out the responsibilities of the owner, the coordinator of the radiation protection program, the X-ray equipment operator, the prescribing dental practitioner, the expert in radiation protection, and repair and maintenance personnel for the safe installation, operation and control of the equipment. It also sets out practices to minimize radiation doses to patients, staff and the public.

### Section B: Facility and Equipment Requirements

This section sets out requirements for the facility design and minimum equipment construction and performance standards.

### Section C: Quality Assurance Program

This section sets out requirements for quality assurance programs including acceptance testing and quality control procedures.

The contents of this document are built upon and generally align with existing Canadian and international standards and guidelines. This includes Schedule II, Part II of the *Radiation Emitting Devices Regulations*, which regulates the construction and functioning of dental X-ray

equipment, and international guidance documents such as the National Council on Radiation Protection and Measurements (NCRP) Report No. 145 and Report No. 177 (Radiation Protection in Dentistry), the European Commission (EC) Issue No. 136 (European guidelines on radiation protection in dental radiology), and International Electrotechnical Commission (IEC) standards for dental X-ray equipment.

## Introduction

Dental radiography is one of the most valuable tools used in dental health care. It is used in the diagnosis of physical conditions that would otherwise be difficult to identify, as well as to assist in the planning of treatment. In the past twenty years, there have been numerous technological advances in dental radiography, including the introduction of digital image receptors replacing the use of film, cone beam computed tomography equipment, and hand-held X-ray devices.

The radiation dose from a properly conducted dental X-ray procedure is generally low in comparison to other medical imaging modalities<sup>1,2,3</sup>, and the annual dose received from natural background radiation<sup>4</sup>. While the science of low dose radiation is evolving, the current radiation protection risk model assumes that any radiation exposure may cause stochastic health effects (namely cancer), the probability of which is proportional to the dose<sup>5,6</sup>; therefore, any procedure involving exposures to ionizing radiation must be carefully managed. The radiological protection community recommends the use of the ALARA (As Low As Reasonably Achievable) principle. This approach to radiation protection manages and controls exposures to personnel and the general public to as low as is reasonably achievable, taking into account social and economic factors. The health risk associated with well-conducted dental X-ray procedures is typically very small and the benefit of appropriately justified imaging for directing patient care far outweighs these risks.

There are four main aspects of radiation protection to be considered in dental radiography:

1. Patients should not be subjected to unnecessary radiographic imaging procedures. This means that the procedures are ordered with justification, and when the diagnostic information cannot be obtained otherwise.
2. When a radiographic imaging procedure is required, it is essential that the patient be protected from excessive radiation exposure during the procedure by ensuring that only the minimum radiation dose is applied to obtain the diagnostic information required.
3. It is necessary that personnel within the facility be protected from excessive exposure to radiation during the course of their work.
4. Personnel and the general public in the vicinity of such facilities require adequate protection from stray radiation.



While in some cases regulatory dose limits have been established for occupationally-exposed personnel and the general public, these limits do not apply to doses received by a patient undergoing medical X-ray procedures. For patients, the risk associated with the exposure to radiation must always be weighed against the clinical benefit of an accurate diagnosis or treatment. There must always be a conscious effort to reduce patient doses to the lowest practical level consistent with optimal quality of diagnostic information. Through close cooperation between prescribing dental practitioners, the coordinator of the radiation protection program, X-ray equipment operators, experts in radiation protection, and any other support staff, it is possible to achieve an effective radiation protection program and maintain a high quality dental radiography program.

## Dental X-ray Modalities

This section describes the types of dental X-ray technologies that are covered in this Safety Code.

### Intra-oral

Intra-oral dental radiography consists of an image receptor that is placed inside the mouth of the patient, while the X-ray source is positioned outside the mouth. The X-ray beam must pass through the targeted area of the patient to reach the image receptor. The image receptor should be placed in a positioning device which aids in alignment of the cone of the X-ray source assembly. The images produced by intra-oral equipment are projection radiographs. Intra-oral radiographs are the most common type of dental radiographs.

### Conventional

For conventional intra-oral equipment, the X-ray source is attached to a movable positioning arm that is mounted on the wall. The control panel and irradiation switch are generally affixed to a wall, which is not in the path of the primary beam, at a distance of greater than 2 m from the X-ray source assembly, or behind appropriate shielding.

### Transportable

Transportable refers to equipment that is intended to be moved from one place to another, whether or not it is connected to a power supply and without an appreciable restriction of range. Transportable intra-oral equipment can be mounted on a stand with a corded or remote irradiation switch that allows the operator to stand more than 2 m from the X-ray source assembly. Mobile equipment is a subset of transportable equipment; it is intended to be moved from one location to another while supported by its own means, such as a mechanical stand on wheels.

## **Hand-held**

Hand-held intra-oral equipment is a type of transportable equipment that can be held in the hand of the operator, while in operation, and can also be placed on a stand and operated with a corded or remote irradiation switch. Hand-held equipment must only be held by hand when it is not reasonably feasible for it to be supported on a stand and used remotely with the corded or remote irradiation switch.

## **Extra-oral**

Extra-oral dental radiography consists of the X-ray source and the image receptor both being outside of the mouth of the patient. Unlike intra-oral radiography, the X-ray beam must pass fully through the patient to reach the image receptor. Extra-oral radiography consists of three modalities:

### **Panoramic**

Panoramic radiography is a form of linear tomography where the X-ray source and image receptor rotate synchronously around the head of the patient to produce a two-dimensional radiograph for the entire dentition, or a portion thereof. The X-ray beam is collimated to a thin vertical strip. Only a thin area (the focal trough) around the teeth is in focus, while anatomy in front of or behind the teeth is blurred. For film panoramic images, the focal trough is defined by the coordinated movement of the rotating X-ray source and horizontal translation of the image receptor.

### **Cone Beam Computed Tomography**

Cone Beam Computed Tomography (CBCT) is a volumetric radiography technique where the X-ray source and image receptor rotate around the head of the patient acquiring many two-dimensional radiographic views. These views are combined using a computer to produce a three-dimensional image. The volume can also be viewed as a series of two-dimensional tomographic slices. Some CBCT machines can generate panoramic images and other reconstructed views (e.g. lateral and poste-anterior cephalometric images, and cross section views).

### **Cephalometric**

Cephalometric radiography is a form of projection radiography where the image receptor remains stationary. The X-ray source is either stationary, in which case the X-ray exposure is a “snapshot” as in conventional medical radiography, or the X-ray source is a horizontally collimated thin beam that is scanned across the patient. Cephalometric radiography produces a two-dimensional projection radiograph of the patient.

## Section A: Responsibilities and Protection

### A.1.0. Responsibilities and Qualifications of Personnel

Although staff responsibilities described below are grouped separately, to obtain the optimal level of radiation safety and image quality, it is imperative that full cooperation exists among all concerned parties. Provincial and territorial professional orders and regulations may also establish requirements relating to who can perform specific actions or roles outlined in this Safety Code, including the responsibilities and qualifications described in this section. The authorities listed in Appendix I should be contacted for details of the regulatory requirements of individual provinces and territories.

#### A.1.1. Owner

The responsibility for radiation safety of a dental facility rests with the owner. The owner is defined as the person or group of persons in control of the possession and use of dental X-ray equipment. The owner may be an individual, a corporation, a district, a province or some other entity.

The following section lists the specific radiation safety tasks which are the responsibility of the owner. The owner may delegate the tasks to qualified staff. How these tasks are delegated will depend on the number of staff members, the nature of the operation and on the number of dental X-ray units owned.

##### A.1.1.1. Responsibilities of Owner

The owner is responsible for:

1. ensuring that the equipment and facilities in which the equipment is installed and used meet all applicable federal, provincial or territorial radiation safety standards and regulatory requirements (e.g., equipment registration);
2. ensuring that a radiation safety program is developed, implemented and maintained for the facility;
3. establishing safe working conditions;
4. consulting with the appropriate government agencies to determine any radiation safety requirements:
  - (i) when a new facility is being constructed, or modifications of an existing one are planned, or when existing X-ray equipment is moved to another location or premises,

- (ii) when dental X-ray equipment is purchased, and to register the equipment with the appropriate regulatory authority (as outlined in Appendix I) if required, and
  - (iii) to set periodic scheduled inspections for the facility. In some jurisdictions, the regulatory authority responsible for inspections has the mandate for setting inspection schedules
5. ensuring that the equipment functions properly through ongoing maintenance by repair and maintenance personnel (See Section A.1.6) and replacement of unsafe equipment or equipment that is not compliant with provincial/territorial regulations;
  6. ensuring that the X-ray equipment has an active Canadian Medical Device Licence at the time of purchase;
  7. ensuring that professional qualifications of all personnel are maintained, as outlined in Sections A.1.2.1, A.1.3.1, 1.4.1, and 1.5.1;
  8. designating the coordinator of the radiation protection program for the facility;
  9. ensuring that the roles of the personnel described below are carried out by one or more designated persons who are qualified and trained to do so, in accordance with jurisdictional requirements;
  10. ensuring that employees are not being exposed to doses exceeding the limits in Appendix II of the present document.

### **A.1.2. Coordinators of the Radiation Protection Program**

The coordinator of the radiation protection program may be the dentist or other qualified staff member. Some provincial/territorial jurisdictions have a regulatory requirement for an X-ray Safety Officer in dental facilities with X-ray equipment, thus in these jurisdictions the X-ray Safety Officer would be the coordinator.

#### **A.1.2.1. Qualifications for Coordinator of the Radiation Protection Program**

The coordinator of the radiation protection program **must**:

1. possess qualifications required by any applicable federal, provincial, or territorial regulations or statutes including certification by an organization as required and recognized by the responsible regulatory authority, and
2. acquire re-qualification or continuing education training according to any applicable federal, provincial, or territorial regulations or statutes and by an organization that is recognized by the responsible regulatory authority.

#### **A.1.2.2. Responsibilities of the Coordinator of the Radiation Protection Program:**

The coordinator of the radiation protection program **must**:

##### **Procedures**

1. ensure that safe operating procedures are established and are followed, and report any non-compliance to the X-ray equipment operator and owner;
2. review the safety procedures periodically and update them to ensure optimum patient and operator safety;

##### **Equipment and Facility**

3. ensure acceptance testing is performed on all new, modified, or repaired dental X-ray equipment prior to clinical use (See Section C.2.0);
4. carry out routine checks of equipment and facility safety features;
5. ensure that presettings and loading factors (values which influence the X-ray tube load, such as tube voltage, current and time of exposure) for all dental X-ray devices are optimized to produce minimum exposure required for diagnostically acceptable images, in consultation with the X-ray equipment operator, dentist, device manufacturer, and an expert in radiation protection, as needed;
6. keep records of radiation surveys, including summaries of corrective measures recommended and/or instituted (See Section B5.1);

##### **Quality Assurance & Quality Control Program**

7. implement and maintain an effective quality assurance program for the facility, including quality control testing procedures and record keeping (See Section C);
8. ensure that quality control monitoring of dental X-ray equipment, image processor and ancillary equipment is carried out;
9. maintain all records of the Quality Assurance program and records pertaining to the performance of dental X-ray equipment for the facility;

##### **Operator Safety**

10. declare personnel who are to be considered radiation workers where they may receive an annual radiation dose in excess of 1 mSv, in consultation with an expert in radiation protection;
11. organize the participation in a dosimetry service for personnel, as determined to be necessary (see item 10 above);

12. keep records of occupational exposures received by personnel participating in a dosimetry service, and investigating any annual exposure received by personnel in excess of 1 mSv;
13. investigate each known event or suspected case of excessive abnormal exposure to patients and staff, in consultation with the X-ray equipment operator, device manufacturer, and an expert in radiation protection, as needed, to determine the cause and to take remedial steps to prevent its recurrence;

### **Training**

14. ensure that X-ray equipment operators are trained in the operation of each type of equipment to be used;
15. instruct X-ray equipment operators and other personnel participating in X-ray procedures in radiation protection practices;
16. ensure that unqualified X-ray equipment operators-in-training and inexperienced personnel only operate dental X-ray equipment under the direct on-site supervision of a qualified operator;
17. disseminate rules of radiation safety and ensure that staff are made aware of them;
18. ensure that X-ray equipment operators understand the recommendations of this Safety Code; and,
19. ensure documentation of education and training is maintained for all operators. Retention times for such records may be specified by federal/provincial/territorial requirements.

## **A.1.3. X-ray Equipment Operators**

### **A.1.3.1. Qualifications of X-ray Equipment Operators**

The X-ray equipment operator **must**:

1. through professional development and/or clinical training, possess qualifications and authorizations required by the applicable federal, provincial or territorial regulations or statutes to operate each type of dental X-ray equipment that will be used for patient imaging (e.g. CBCT, hand-held dental X-ray equipment). For clarification regarding the regulatory requirements, contact the applicable regulatory authority listed in Appendix I;
2. have documented training in
  - (i) the safe operation of the X-ray equipment and accessories used in the facility,
  - (ii) the radiological procedure being performed,
  - (iii) patient positioning for accurate localization of regions of interest,

- (iv) routine manufacturer-specified quality assurance procedures, if necessary, and
  - (v) radiation protection procedures and measures;
3. acquire re-qualification or continuing education training according to any applicable federal, provincial, or territorial regulations or statutes, and according to a recognized standard. For clarification regarding regulatory requirements, contact the applicable regulatory authority listed in Appendix I.

#### **A.1.3.2. Responsibilities of X-ray Equipment Operators**

All dental X-ray equipment operators have the responsibility of carrying out prescribed dental radiological procedures in a manner which does not cause any unnecessary exposures to patients, themselves, other workers and the public in the facility.

All dental X-ray equipment operators **must**:

1. be familiar with, and have access to, the manufacturer's operator manual for the specific dental X-ray equipment used in the facility;
2. recognize the radiation hazards associated with their work and take measures to minimize them;
3. have a thorough understanding of safe working methods and appropriate techniques and procedures, including the appropriate use of personal protective equipment;
4. strive to eliminate unnecessary radiographic procedures by reducing the number of retakes, and reduce all patient radiation exposures to the lowest practical values while maintaining acceptable diagnostic image quality;
5. participate fully in the established quality assurance program for the facility, including reporting any change in equipment performance to the Coordinator of the Radiation Protection Program;
6. if they may receive an annual dose in excess of 1 mSv, as declared by the coordinator of the radiation protection program, monitor their radiation exposures with the use of a personal dosimeter, and be aware of their annual occupational dose;
7. record the patient radiographs in a registry, and maintain records of retakes (See Section C3.2, item M9), and;
8. understand and comply with the recommendations of this Safety Code.

#### **A.1.4. Prescribing Dental Practitioner**

##### **A.1.4.1. Qualifications of Prescribing Dental Practitioners**

The prescribing dental practitioner **must**:

1. possess qualifications required by the applicable federal, provincial, or territorial regulations or statutes and be licensed according to the recognized standard in the applicable jurisdiction; and
2. acquire re-qualification or continuing education training according to the applicable federal, provincial, or territorial regulations or statutes, and according to the recognized standard in the applicable jurisdiction. For clarification regarding regulatory requirements, contact the applicable regulatory authority listed in Appendix I.

#### **A.1.4.2. Responsibilities of Prescribing Dental Practitioners**

The prescribing dental practitioner is the individual authorized to prescribe dental X-ray procedures. The main radiation protection responsibility of the prescribing dental practitioner is to ensure that the use of X-rays is justified. Currently, dental therapists in all jurisdictions and dental hygienists in some jurisdictions are authorized by legislation to order X-ray examinations. In such cases, the responsibilities of the prescribing dental practitioner listed below would apply to those individuals. It is recommended to contact the appropriate provincial or territorial radiation safety agencies, listed in Appendix I, for information on any applicable provincial or territorial statutes or regulations.

The prescribing dental practitioner **must**:

1. prescribe a dental X-ray examination based on professional experience, judgement and consideration of current prescribing guidelines ( See Section A.3.1);
2. be aware of the radiation risk associated with radiographic procedures and be able to explain them to the patient;
3. give consideration to alternative, non X-ray utilizing, examinations;
4. consider whether recent images are available which would eliminate the need for additional X-ray exposures;

and **should**:

1. be confident that the procedure will improve the patient diagnosis and/or treatment sufficiently in comparison with alternate, non X-ray utilizing methods of diagnosis and/or treatment; and
2. remain informed of safety updates and the availability of new equipment, supplies and techniques that could further improve the diagnostic ability of X-ray procedures and decrease exposure.



### A.1.5. Expert in Radiation Protection

An “Expert in radiation protection”, as referenced throughout this Safety Code, is a person with extensive knowledge and expertise in radiation protection. For example, individuals in the following professions may have such expertise: medical physicist, biomedical engineer, radiation protection physicist, physical engineer, or radiation protection specialist.

#### A.1.5.1. Qualifications of Experts in Radiation Protection

According to any professional designations they have, the expert in radiation protection **must**:

1. possess qualifications required by the applicable federal, provincial, or territorial regulations or statutes and be licensed according to the recognized standard in the applicable jurisdiction; and
2. acquire re-qualification or continuing education training according to the applicable federal, provincial, or territorial regulations or statutes, and according to the recognized standard in the applicable jurisdiction. For clarification regarding regulatory requirements, contact the applicable regulatory authority listed in Appendix I.

#### A.1.5.2. Responsibilities of experts in radiation protection

The role of the expert in radiation protection is to support the owner and coordinator of the radiation protection program in ensuring radiation safety of the dental facility. Specific functions of such support are referenced by use of the term “Expert in radiation protection” throughout the guidance in this Safety Code, such as conducting facility radiation surveys, assessing the need for use of personal dosimeters, calculating facility shielding requirements, and performing optimization of doses from X-ray devices.

### A.1.6. Repair and Maintenance Personnel

Personnel in this group perform maintenance and repairs on dental X-ray generators, control systems, imaging systems and their operating software. This function may be contracted to an outside service provider, or to the equipment manufacturer.

The repair and maintenance personnel **must**:

1. have knowledge and training in repair and maintenance of radiological imaging equipment, and radiation protection principles and procedures;
2. follow manufacturers' recommendations for the repair and maintenance of equipment whenever feasible;
3. ensure that, upon completion of a repair or maintenance procedure, the equipment meets the required regulatory standards and/or manufacturer specifications;

4. ensure that all repair and maintenance procedures are recorded and communicated to the owner and other appropriate staff;
5. review the maintenance procedures periodically and update them to ensure optimum patient and operator safety;
6. report any non-compliance with the established safety procedures to the owner of the equipment, and;
7. communicate, if necessary, to staff the need for appropriate acceptance testing, baseline setting and quality control testing.

## **A.2.0. Procedures for Minimizing Radiation Exposure to Personnel**

The guidance outlined in this Section is primarily directed toward occupational health protection. However, adherence to these procedures will also, in many instances, provide protection to visitors and other individuals in the vicinity of a dental facility with X-ray equipment. These safe work practices should be regarded as a minimum, to be augmented with additional requirements, when warranted, to cover special circumstances in particular facilities.

To achieve optimal safety, operators of dental X-ray equipment must make every reasonable effort to keep radiation exposures to themselves and to others as far below the limits specified in Appendix II as achievable (i.e. ALARA).

### **A.2.1. General Requirements and Recommendations**

#### **Equipment & Room**

1. Dental radiographic equipment must only be operated by qualified individuals or persons in training who are under direct supervision. Qualified individuals shall be trained and authorized, as per Section A1.3.1, in the safe use of the equipment and the procedures being performed.
2. An X-ray room must not be used for more than one radiological investigation simultaneously.
3. X-ray machines which are energized and ready to produce radiation must not be left unattended in a location with unrestricted access.
4. The operation of dental X-ray equipment should be controlled from the control panel located in a properly shielded area (as per Section B.1.2.2). In special circumstances, where the operator is required to control the loading while at the side of the patient, protective equipment must be worn (See Section B.4.1).

5. An X-ray tube housing must not be held by hand during operation unless it is specifically designed for hand-held use (See Section A.2.2 for minimizing radiation exposure to personnel from hand-held devices).

### **Procedures – Personnel**

6. Except for those persons whose presence is essential, all persons must leave the room when the irradiation is carried out.
7. Personnel must, at all times, keep as far away from the X-ray beam as practicable. If personnel are not initiating the X-ray exposures from an adequately shielded location, then a minimum distance of 2 m must be maintained between the operator and the intra-oral, panoramic or cephalometric X-ray source. In addition, the position of the operator must not be in the path of the primary X-ray beam. For CBCT devices, shielding requirements must always be assessed (refer to Section B.1.3). Distance alone without intercepting shielding is typically not sufficient due to the increased scatter radiation that is produced from CBCT exposures<sup>7,8</sup>.
8. Operators of extra-oral dental X-ray equipment must be able to see the patient for the duration of the X-ray exposure and must be able to communicate with the patient and/or attendants.
9. Operators should be able to control and prevent entry into the X-ray room during any exposure.
10. All operators of dental X-ray equipment, together with personnel who routinely participate in radiological procedures, and others, likely to receive an annual radiation dose in excess of 1 mSv must be declared radiation workers and monitor their radiation exposures with the use of a personal dosimeter. In general, personnel only operating dental X-ray equipment are not declared radiation workers as they do not typically receive annual radiation doses in excess of 1 mSv. The results of the facility radiation survey conducted by an expert in radiation protection (See Section B.5.0) must be considered in assessing the need for personal dosimetry. Where the annual occupational dose may exceed 1 mSv, personnel must wear a personal dosimeter for the first year of operation to establish a baseline annual dose received by personnel. After review of the first annual radiation dose (In consultation with an expert in radiation protection as needed), along with consideration of any potential variation in factors contributing to future radiation dose, if the dose is expected to be below 1 mSv/yr the use of a personal dosimeter can be discontinued.. For additional guidance on personal dosimetry for hand-held X-ray devices, see Section A.2.2.4.
11. Each personal dosimeter must be assigned to one individual only and must not be shared. They must be worn and stored according to the recommendations of the dosimetry service provider. When a protective apron is worn, the personal dosimeter must be worn under the apron.

12. Where an unusually high radiation dose compared to previous dosimetry reports is received by any one person, appropriate remedial steps must be taken, such as investigation by an expert in radiation safety to determine the reasons for the elevated exposure and implementation of corrective actions to ensure that staff doses are ALARA. Depending on the reasons for the elevated exposure, the corrective actions may include refresher training, repairing malfunctioning equipment or the redistribution of the workload among all staff who are qualified. The type of corrective actions should specifically address the problem that caused elevated exposure.
13. All personal dosimetry records must be maintained for the lifetime of the facility.
14. If an X-ray operator declares to an employer that they are pregnant, the employer must take appropriate steps to ensure that the X-ray operator's work duties during the remainder of the pregnancy are compatible with the recommended dose limits as stated in Appendix II. Depending on the type of work being performed by the employee, it may not be necessary to remove a pregnant staff member from their duties of operating the dental X-ray equipment. It is recommended that the decision to remove pregnant workers from their duties include consideration of the radiation exposure risks associated with the employee's duties, as determined by an expert in radiation protection. In general, for the performance of dental X-ray examinations, there is no need to remove or restrict the duties of dental X-ray equipment operators during pregnancy because the radiation exposure is typically far below the dose limit under normal working conditions.
15. Deliberate irradiation of an individual for the sole reasons of demonstration, equipment evaluation, training purposes or practicing technique must never occur.
16. The primary beam of the dental X-ray device must not be directed towards any personnel or the public unless appropriate shielding intercepting the primary beam is in place.

#### **Procedures – Patients**

17. When there is a need to physically support patients, patient-holding devices should be used. If parents, escorts or other personnel are called to and agree to assist or comfort patients, they must be made aware of risk with X-ray radiation. They must be provided with protective aprons and be positioned to avoid the primary X-ray beam. No person must perform these duties on a daily basis.
18. The intra-oral dental image receptor should be fixed in position with a holding device, whenever possible, otherwise it should be held by the patient, a parent or escort of the patient. If parents or escorts are called to hold the image receptor, they must be provided with protective aprons, and be positioned to avoid the X-ray beam. The holder of the image receptor should use forceps or another device to support the image receptor such that their hand is not within the primary X-ray beam. The dental practitioner, X-ray equipment

operator, or other personnel must not hold the image receptor in place during the procedure.

### A.2.2. Requirements for Hand-held Dental X-ray Devices

Provinces and territories may have specific requirements for the use of hand-held dental X-ray devices. Facilities that fall under provincial or territorial jurisdiction should consult the regulatory authority listed in Appendix I for their respective region to obtain detailed information on any provincial or territorial statutory or regulatory requirements.

#### Conditions of Use

1. A hand-held dental X-ray device must only be used in exceptional situations, due to the location where imaging is being undertaken and/or the conditions of the patient, where it is not reasonably feasible to use a device that is wall-mounted or mobile/transportable that permits the operator to initiate X-ray exposures from a distance of at least 2 m from the device.
2. Further to the above, hand-held dental X-ray devices must only be held by hand when it is not reasonably feasible for it to be supported on a stand and used remotely with the corded or remote irradiation switch (which allows the operator to stand at least 2 m from the device) or when specific patient needs necessitate hand-held use to obtain a diagnostically acceptable image.
3. For any location where a given hand-held dental X-ray device is used, all persons, except the operator and patient, must be at least 2 m from the hand-held dental X-ray device during operation and access to the controlled area where the imaging is performed must be restricted.
4. For at least the first year of operation of a hand-held dental X-ray device where the device is routinely held by hand, each operator must wear a personal dosimeter until a baseline annual radiation dose is established. The personal dosimeter is to be placed on the body at waist height, but not located directly behind the hand-held device such that the device blocks the dosimeter<sup>9</sup>. After review of the first annual radiation dose (In consultation with an expert in radiation protection as needed), along with consideration of any potential variation in factors contributing to future radiation dose, if the dose is expected to be below 1 mSv/yr the use of a personal dosimeter can be discontinued. Any significant changes to workload, equipment or techniques would require a new review of the risk by an expert in radiation protection, including whether another fixed evaluation period or continuous personal monitoring is required.
5. The coordinator of the radiation protection program must ensure that all regulatory dose limits are met for occupationally-exposed dental workers and members of the public through appropriate use of distance and shielding and the ALARA principle is applied to

minimize the radiation dose to patients and surroundings to a level as low as reasonably achievable.

### **Procedures**

6. Operators of hand-held dental X-ray devices must ensure proper positioning of their body behind the backscatter shield. This typically means the X-ray beam is maintained horizontally, with the backscatter shield oriented vertically, when the patient is in a seated position with his head positioned as to acquire a diagnostic radiograph.
7. The distance from the end of the cone of the device to the patient must be minimized. Many intra-oral image receptor holders with an aiming ring have a mechanism that will interfere with the backscatter shield of a hand-held dental X-ray device, creating a significant gap between the end of the cone and the patient. When using a hand-held dental X-ray device, an appropriate image receptor holder that does not interfere with the backscatter shield and allows the cone of the device to be placed as close as possible to the patient must be used.
8. Hand-held dental X-ray devices must be stored in a locked cabinet or area when not in use to prevent accidental damage, theft or unauthorized use.
9. If a hand-held dental X-ray device has incurred any form of potential damage, such as impact damage due to being dropped, acceptance testing must be performed on the device to ensure proper functioning (see Section C.2.0).

### **Training and Education**

10. Operators of hand-held dental X-ray devices must read and comply with all safety information and instructions provided in the manufacturer's accompanying documentation prior to operation of the device.
11. Operators of hand-held dental X-ray devices must be trained for use of the device, as provided by the manufacturer or a service provider with appropriate expertise. In addition to requirements of Section A.1.3.1, training must include:
  - (i) Appropriate justification required for hand-held use of the device, as opposed to using the device mounted on a stand or a permanent wall-mounted unit.
  - (ii) Proper orientation of the device to ensure the operator is appropriately positioned behind the backscatter shield.
  - (iii) Consideration of means, such as shielding, to ensure appropriate radiation protection of personnel and the public for any location in which the device is used.
  - (iv) Prevention of unauthorized use of the device as specified by the applicable regulatory authority.

- (v) Any specified training required by the applicable regulatory authorities.

### **A.3.0. Procedures for Minimizing Radiation Exposure to Patients**

The largest single contributor of man-made radiation exposure to the population is medical radiology, which includes dental radiology. In total, medical use of X-rays accounts for more than 90% of the total man-made radiation dose to the general population<sup>4</sup>.

The risk to the individual patient from a single optimized dental X-ray examination is low relative to other medical imaging procedures and the benefit to each individual from a justified dental X-ray examination outweighs the risk. However, the risk to a population is increased by increasing the frequency of X-ray examinations and by increasing the number of persons undergoing such examinations. For this reason, it is important to minimize through proper justification the number of dental radiographs taken and the number of persons examined radiographically, as well as to optimize the doses associated with the examinations.

To minimize the radiation risk, it is essential that patients only be subjected to justified radiological examinations and when a radiological examination is required, patients must be protected from excessive radiation during the examination.

The guidelines for the protection of the patient, outlined in this section, are directed toward the prescribing dental practitioner and the X-ray equipment operator. They are intended to provide guidance for the elimination of unnecessary dental radiological examinations and for minimizing doses to patients when radiological examinations are necessary.

#### **A.3.1. Guidelines for the Prescription of Dental X-ray Examinations**

Prescribing a dental X-ray examination should be based on professional experience, judgment, and current prescribing guidelines. Unnecessary radiation exposures of patients can be significantly reduced by ensuring that all X-ray examinations are clinically justified. This can be done by adhering to certain basic recommendations as presented below.

1. The request for a dental X-ray examination of a patient should be based on history and clinical evaluation of the patient and should be for the purpose of obtaining diagnostic information, provision of safe and efficient treatment or for monitoring patient treatment.
2. Routine or screening examinations, in which there is no prior clinical evaluation of the patient and no clinical justification, should not be performed, including examinations of children to monitor dental development. Dental X-ray examinations should only be performed after a clinical examination of the patient has determined an expected health benefit to the patient.

3. The possibility of performing non-radiographic examinations should first be considered. Further, it should be confirmed that there are no previous X-ray images available which would avoid the need for additional X-ray exposures.
4. When a patient leaves or is transferred from one dental practitioner to another, any relevant images and reports should accompany the patient and should be reviewed by the consulting dental practitioner.
5. When prescribing a dental X-ray examination, the dental practitioner should document and specify precisely the clinical indications and information required.
6. The number of radiographic views required in an examination must be kept to the minimum practicable, consistent with the clinical objectives of the examination.
7. Due to radiation dose to the patient<sup>1,4,10,11</sup>, CBCT imaging must be prescribed only if the clinical objectives cannot be satisfactorily met by other lower dose dental X-ray modalities (intra-oral, panoramic, or cephalometric).
8. In prescribing any X-ray examination of pregnant or possibly pregnant persons, full consideration must be taken of the consequence of foetal irradiation. In the case of dental X-ray examinations, it is generally accepted that the level of radiation to the foetus from dental X-rays is extremely low when the abdomen is not directly exposed<sup>12,13</sup>. For dental X-rays of pregnant patients, the Canadian Dental Association states that "Elective procedures may be deferred until after the pregnancy. Pregnant patients requiring essential and/or emergency treatment should receive the minimum number of radiographs needed for diagnostic purposes."<sup>14</sup>
9. If a radiograph contains the required diagnostic information, repeat procedures must not be prescribed simply because the radiograph is not of the "best" diagnostic quality.
10. A patient's clinical records must contain details of all radiographic examinations carried out, including indications and findings.

The following documents provide additional guidance on prescription criteria for dental X-rays, and may be used to aid in assessing the need for dental radiography:

- For general dental radiographs, *Dental Radiographic Examinations: Recommendations For Patient Selection And Limiting Radiation Exposure* (American Dental Association/Food and Drug Administration), revised 2015<sup>15</sup>.
- For general dental radiographs, *Radiation Protection No. 136: European Guidelines on Radiation Protection in Dental Radiology* (European Commission), 2004<sup>16</sup>.
- For dental Cone Beam Computed Tomography, *Radiation Protection No. 172: Cone Beam CT For Dental And Maxillofacial Radiology* (European Commission), 2012<sup>8</sup>.



- For dental Cone Beam Computed Tomography, *NCRP Report No. 177 - Radiation Protection in Dentistry and Oral & Maxillofacial Imaging* (NCRP), 2019<sup>17</sup>

### A.3.2. Guidelines for Protecting the Patient during Dental X-ray Examinations

Next to the elimination of unnecessary X-ray examinations, the most significant factor in reducing patient dose is ensuring that examinations are performed using proper technique. It is the responsibility of the operator and the prescribing dental practitioner to be aware of this and to know how to carry out a prescribed examination with the lowest practical dose to the patient.

The guidelines that follow are intended to provide guidance to the operator and the prescribing dental practitioner in exercising their responsibility towards reduction of radiation exposure to the patient.

#### A.3.2.1. General Guidelines for Dental X-ray Examinations

1. The operator must not perform any X-ray examination unless it has been prescribed by the prescribing dental practitioner responsible for the patient.
2. The dose to the patient must be kept to the lowest practical value, consistent with clinical objectives and without loss of essential diagnostic information. To achieve this, techniques appropriate to the equipment available should be used and evaluated from time to time in terms of effectiveness. It is recommended to establish an optimized techniques chart, including settings for field of view and resolution where appropriate, when using X-ray units which do not have preprogrammed anatomical feature settings.
3. Fluoroscopy must not be used in dental examinations.
4. Dental radiography must not be carried out at nominal X-ray tube voltages below 60 kilovolts.
5. Dental X-ray equipment must be maintained and monitored routinely through a Quality Assurance program (See section C) and preventative maintenance, including routine monitoring of the quality of radiographs to ensure that they satisfy diagnostic requirements with minimal radiation exposure to the patient.
6. The patient must be provided with a thyroid shield when it will not interfere with the required diagnostic information of the examination<sup>4,12,17,18,19</sup> (See Section A3.2.3, item 1). The use of a thyroid shield is especially important in children<sup>16</sup>, as the thyroid gland in children is particularly sensitive to radiation. The thyroid shield should have a lead equivalence of 0.25 mm of lead up to a peak X-ray tube voltage of 100 kV, and 0.35 mm of lead at greater than 100 kV and less than 150 kV.

7. With the exception of CBCT procedures, the use of a lead apron is not required for the patient during routine dental X-ray procedures, if all other recommendations for limiting patient radiation exposure are respected (See Section A.3.0), as the dose to the patient will not be significantly affected by abdominal shielding; however, a lead apron may be used to aid in patient comfort regarding fears of radiation. For CBCT procedures, the patient should be provided with a lead apron when it will not interfere with the required diagnostic information of the procedure, as there is uncertainty and a lack of consensus regarding use of lead aprons for patients with CBCT<sup>8,12,13,16,17,20,21,22,23,24</sup>.
8. The X-ray beam must be well collimated and aligned with the patient's head to restrict the beam as much as practicable to the area of diagnostic interest.
9. For film-based imaging, the film processing technique should ensure optimum development and should be in accordance with the recommendations given in Section B.3.1. Sight developing, i.e. increasing or decreasing the developing time according to visual inspection of film density while the film is still in the developer, must not be done as it is prone to errors.
10. Dental X-ray films must be examined with a viewbox specifically designed for this purpose.
11. The X-ray equipment operator should evaluate the resulting images to verify that the techniques being used are producing diagnostic quality images and that the X-ray equipment is functioning correctly.
12. The operator must investigate the cause of the dental X-ray image rejection before repeating the exposure on the same patient. Repeat dental X-ray examinations must not be performed only because an X-ray image may not be of the "best" quality if the image contains the required diagnostic information.
13. Full details of the dental X-ray procedures carried out, including retakes, should be noted in the patient's clinical records.
14. Radiological examinations of children must be performed using optimized techniques which have been modified for size and age.
15. All images captured, whether on film or on digital imaging systems, must remain with the patient records unless they are rejected by the operator for valid predefined quality issues. All rejected images must be collected for use during routine rejection/retake analysis (See Section C.3.2, item M9).
16. If there are selectable image resolution settings, for each image the lowest possible resolution setting that will meet the clinical objective should be used, as this can significantly reduce the dose received by the patient.

### **A.3.2.2. Requirements and Recommendations for Intra-oral Examinations**

1. Intra-oral radiography should not be carried out at X-ray tube voltages above 70 kV<sup>25</sup>.
2. Rectangular collimation of the X-ray beam must be used, except in occlusal protocols, as it significantly reduces the dose to the patient compared to circular collimation<sup>2,16,26,27,28</sup>. After market adaptors are available for converting any round-headed collimator to rectangular collimation.
3. A film/image receptor holder with an alignment device for the X-ray beam should be used.
4. A long cone (30 cm or longer) should be used, as it reduces the dose to the patient compared to a short cone (20 cm)<sup>29</sup>. The cone must ensure a minimum focal spot to skin distance of 20 cm.
5. For film-based imaging when the implementation of digital radiography is not practicable, E-speed film or faster must be used, and D-speed film must not be used.

### **A.3.2.3. Requirements and Recommendations for Panoramic Examinations**

1. For most protocols with panoramic devices, a thyroid shield should not be used as it will be within the primary X-ray beam and may impact the required diagnostic information. The patient must be provided with a thyroid shield for protocols in which it will not interfere with the required diagnostic information of the examination<sup>4,12,30</sup>.
2. For panoramic radiography, proper patient positioning is particularly important for image quality and to avoid retakes. Light beams for patient positioning, if available on the machine, should always be used to facilitate accurate patient positioning.
3. For film-based panoramic radiography, the fastest screen-film combination that is consistent with diagnostically acceptable results should be used.
4. For patient safety, to ensure the patient has not moved prior to imaging, the operator must be able to observe the patient during the exposure. This may be achieved using an appropriately shielded window, camera/monitor, a mirror, or other means of viewing the patient.
5. When only a panoramic image is prescribed, it must be obtained from a true panoramic exposure, not a panoramic image reconstructed from a CBCT exposure, which can result in a significantly higher dose to the patient<sup>31</sup>.

### **A.3.2.4. Guidelines for Cone Beam Computed Tomography Examinations**

1. The smallest available field of view setting that will meet the clinical objective must be used, to minimize the dose to the patient<sup>1,32</sup>.

2. The lowest available resolution setting, or largest voxel size, that will meet the clinical objective must be used, as it can significantly reduce the dose to the patient<sup>1,32</sup>.
3. For patient safety, to ensure patient has not moved prior to imaging, the operator must be able to observe the patient during the exposure. This may be achieved using an appropriately shielded window, camera/monitor, a mirror, or other means of viewing the patient.

### **A.3.3. Guidelines for Optimizing Dental X-ray Examinations**

As part of the ALARA principle, it is important that presets and techniques for dental X-ray devices are optimized for each procedure performed in the facility to ensure patient radiation doses are minimized. An optimized X-ray procedure uses the least amount of X-ray exposure required to create a diagnostically acceptable image. Optimization of dental X-ray devices, including ongoing periodic assessment after initial installations, must be done by the vendor or dental service provider through which the device was purchased, or by an expert in radiation protection. Optimization also requires cooperation and input from the dental practitioner who is authorized to interpret patient images. The guidelines in the subsequent section help ensure optimization of dental X-ray devices.

#### **A.3.3.1. General Guidelines for All Dental X-ray Examinations**

1. Establishment of optimized presets and optimized techniques for dental X-ray devices must be done upon initial installation and prior to clinical use of the device, and should be included as a requirement in the purchase contract of new dental X-ray devices.
2. Optimization must include presets and techniques specific for imaging of pediatric patients, where radiation output of the device is typically reduced compared to adult patient imaging.
3. Each element of the imaging chain must be optimized, such as display monitors and post-processing techniques for image data from digital image receptors, and chemical processing times/temperatures and viewboxes for film.
4. When changing from film to a digital image receptor, the techniques (including preprogrammed anatomical feature settings) must be re-optimized for the digital image receptor.
5. It is recommended that optimization be performed during annual Quality Assurance testing. Diagnostic Reference Levels (DRLs) and achievable doses should be used as part of the annual assessment of optimization (See Section A.3.3.4).
6. For imaging techniques that are set manually, an optimized techniques chart based on patient size for each device must be affixed on or near the control panel of the X-ray device.

### **A.3.3.2. Guidelines for Intra-oral Examinations**

For intra-oral devices, the image receptor is typically not integrated with the X-ray generator. Loading factors for preset techniques available from the X-ray generator can therefore be further optimized for the specific imaging system being used. An optimized technique chart must be used to manually set techniques if none are integrated to the X-ray generator. The following guidance applies to optimization of intra-oral devices when paired with a specific imaging system:

1. The loading factors for all preset techniques of an intra-oral device, where the loading factors are selectable by anatomical indications (e.g. by buttons for “adult” and “bitewing”), must be optimized based on the results of acceptance testing or quality assurance testing, with the presets on the devices adjusted as required. It should not be assumed that the manufacturer recommended X-ray generator settings for preset techniques will provide optimized radiation doses for a given specific installation of a dental X-ray device and image receptor.
2. For digital intra-oral imaging system, the manufacturer recommended exposure for the image receptor should be consulted when optimising the device, as there is potential variability in the required X-ray exposure among image receptors.
3. If the intra-oral X-ray device has no preset techniques, meaning they are set manually, an optimized techniques chart must be affixed on or near the control panel. The techniques chart will consist of the optimized loading factors based on the results of acceptance testing and quality control testing.

### **A.3.3.3. Requirements and Recommendations for Extra-oral Examinations**

For digital extra-oral X-ray devices, the image receptor is integrated with the X-ray generator, and the devices are typically operated using preset techniques with loading factors set by the manufacturer. The vendor or dental service provider through which the device was purchased, or a third party expert in radiation protection, must evaluate the preset techniques for optimization based on the results of acceptance testing of the device.

### **A.3.3.4. Diagnostic Reference Levels (DRLs) and Achievable Doses (ADs)**

Doses for dental radiographic procedures can vary widely between equipment and facilities (Both for a given technology and level of image quality selected), especially for panoramic and CBCT equipment<sup>1,33</sup>. An effective approach to help minimize this variation and optimize patient dose is the establishment and use of Diagnostic Reference Levels (DRLs)<sup>34</sup>. DRLs provide guidance to manage doses, attempting to ensure that equipment settings and the resulting dose is appropriate for the diagnostic objective

DRLs are typically based on the 75<sup>th</sup> percentile of dose index distributions established from surveys of imaging practice for commonly performed examination types, each of which may

also list clinical indications for which the examination is prescribed. DRLs attempt to summarize what would be considered reasonable application of a measured quantity of ionizing radiation. They can be an effective measure in reducing patient exposures for frequently used examination protocols, while allowing sufficient latitude to manage clinical needs and maintain diagnostic image quality for the clinical purpose intended. They are not regulatory or punitive limits, and can be exceeded where there is clinical need, but they provide thresholds to indicate a rationale should be provided when that practice level is exceeded. The need for a rationale is even stronger when a median dose of a particular examination/device consistently exceeds the DRL.

DRLs may be established at the national (country), regional (multi-national), and local (single large facility or group of facilities in a geographic area) levels. Similarly, Achievable Doses (ADs) represent the median value (50th percentile) of the dose index distribution used to set the DRL value and can represent a second target for further dose optimization activities. DRLs for specific patient groups such as adults and children, and of different sizes where applicable for the imaging device (e.g. CBCT with different jaw size settings available), should be established.

While this Safety Code recommends representative DRLs and ADs, a facility can set their own local values if enough data are available. The facility should create a list of reference doses for their examination protocols for each dental device and use these values within their quality assurance program. DRLs and ADs should be reviewed at least annually to assess their appropriateness. Determination of DRLs and optimization of doses must be assessed during the annual Quality Assurance testing (refer to Section C.3.3) by the service provider through which the device was purchased, or by an expert in radiation protection.

Facilities which fall under provincial or territorial jurisdiction should contact the responsible regulatory authority in their respective region for information on any provincial or territorial statutory or regulatory requirements concerning dose limits. A listing of these responsible agencies is provided in Appendix I.

Table 1 presents representative DRLs and ADs for dental X-ray procedures performed on an average adult patient, including the appropriate dosimetric indicator to use when measuring the dose for each procedure and the relevant conditions of measurement. Note that the values apply to equipment using both film and digital image receptors. These DRL and AD values are as referenced in the National Council on Radiation Protection and Measurements Report No. 172<sup>35</sup>. It should be noted that the DRLs in Table 1 are based on the NCRP survey data from 2012 (U.S. and European data only; no Canadian data available), and as future technological advances cannot be predicted, it is possible that the appropriate values for the DRLs and ADs could change (i.e. lower) over time.

**Table 1. Representative DRLs and ADs for average adult patient in dental X-ray procedures<sup>35</sup>**

Procedure	Dose indicator	DRL	Achievable Dose	Notes
Intra-oral bitewing and periapical	Incident air kerma	1.6 mGy	<ul style="list-style-type: none"> <li>1.2 mGy for E/F speed film</li> <li>0.8 mGy for digital image receptors</li> </ul>	<ul style="list-style-type: none"> <li>Incident air kerma without backscatter measured at end of X-ray tube cone</li> </ul>
Panoramic	Air-kerma area product	100 mGy·cm <sup>2</sup>	76 mGy·cm <sup>2</sup>	<ul style="list-style-type: none"> <li>Air-kerma area product measured with a KAP meter that is attached to the X-ray tube housing and intercepts the entire beam</li> </ul>
Cephalometric	Incident air kerma, or air-kerma area product	0.14 mGy, or 26.4 and 32.6 mGy·cm <sup>2</sup> for children and adults, respectively	0.09 mGy, or 14 and 17 mGy·cm <sup>2</sup> for children and adults, respectively	<ul style="list-style-type: none"> <li>Incident air kerma (mGy) measured with ionisation chamber in-beam</li> <li>Air-kerma area product (mGy·cm<sup>2</sup>) measured with a KAP meter that is attached to the X-ray tube housing and intercepts the entire beam</li> </ul>
Cone Beam CT	Air-kerma area product	Not available	250 mGy·cm <sup>2</sup> (Adult upper first molar implant)	<ul style="list-style-type: none"> <li>No DRL set by NCRP as there is currently a lack of sufficient survey data</li> <li>Achievable dose as proposed by European Commission</li> </ul>

Procedure	Dose indicator	DRL	Achievable Dose	Notes
				Radiation Protection No. 172 <sup>8</sup>

While DRLs (or ADs) serve as an indication of when optimization of radiation doses should be assessed, simply meeting a DRL does not necessarily mean that patient doses have been fully optimized. If the median dose indicator is found to be consistently below the suggested DRL, reasonable efforts to further minimize patient doses are still beneficial and should be pursued in order to attain a dose level that is ALARA while still maintaining sufficient diagnostic image quality for the purpose intended. It may be possible to acquire images of sufficient clinical image quality at doses well below any published DRL or AD values.

Dental DRL values are recommended from distributions of the dose indices air kerma ( $K_{air}$ , mGy) and/or air kerma area product (KAP, mGy·cm<sup>2</sup>). DRLs are based on typical/routine examinations using the standard techniques and loading factors at the facility. Since the same standard exposure settings are used for the majority of dental examinations, a measurement of output with the appropriate settings can be considered as the median incident air kerma for each dental examination protocol on a particular imaging device, or measurements from individual patient exams can be used to establish the DRLs. Separate measurements should be made for exposure settings for adult and child, and for different sizes where applicable for the imaging device<sup>34</sup>.



## Section B: Facility and Equipment Requirements

### B.1.0. Facility Requirements

#### B.1.1. General Criteria

In the planning of any dental facility it must be ensured that persons in the vicinity of the facility are not exposed to levels of radiation which surpass the current exposure limits. Appropriate steps must be taken to ensure the following requirements are met:

1. The radiation levels in controlled areas that are occupied routinely by dental workers must be such that no dental worker is occupationally exposed to more than 20 mSv per year; and
2. The radiation levels in uncontrolled areas must be such that no person receives more than 1 mSv per year.

Appendix II provides a detailed description of recommended dose limits. However, facilities under provincial/territorial jurisdiction may have different limits. While these dose limits establish the maximum exposure levels, in keeping with ALARA facilities can be designed to a lower shielding goal that reduces the exposure of dental workers in controlled areas and individuals in uncontrolled areas to levels below these limits (See Section B.1.2.3). For dental facilities, controlled areas are typically in the immediate areas where the X-ray equipment is used. The workers in these areas are primarily X-ray equipment operators who are trained in the proper use of the equipment and in radiation protection. Uncontrolled areas are those occupied by individuals such as patients (e.g. waiting areas), visitors to the facility, and employees who do not work routinely with or around radiation sources<sup>36</sup>.

In general, radiation levels directly beside dental X-ray equipment are such that the above limits could be exceeded, depending on the design of the equipment, the techniques used and the total workload. However, reduction in radiation intensity can be accomplished with the presence of a suitable shielding barrier between the patient and the operator, a suitable distance from the sources of radiation, or a combination of these, and restriction of persons from all areas in which the respective recommended dose limit could be exceeded.

#### B.1.2. Design and Plan of Dental Facility

The owner is responsible for the radiation safety of the facility, including ensuring plans meet any requirements set forth by the applicable regulatory authority. In the early stages of designing and planning a dental facility, three steps should be taken to ensure the following requirements are met:

- (a) Preparation of facility plans;

- (b) Considerations for room design and layout; and
- (c) Determination of parameters governing shielding requirements.

#### **B.1.2.1. Preparation of Facility Plan**

In order to determine the shielding requirements for a radiographic facility a floor plan must be prepared, clearly identifying the following components:

1. The dimensions and shape of the room where the X-ray equipment is operated, the identification of the rooms by a recognized convention (for example, room number or type of room ) and the physical orientation of the room (a mark indicating north).
2. The location where the X-ray equipment and dental chairs are planned to be placed and the range of movement of the X-ray tubes.
3. The location of the control panel.
4. The location of the exposure switch.
5. The location, use, occupancy level and accessibility of adjacent rooms, as well as rooms above and below the facility.
6. The designation of the adjacent rooms, whether to be designated as controlled areas (mainly occupied by occupationally-exposed dental workers) or uncontrolled areas (mainly occupied by members of the public, including non-occupationally exposed dental workers).
7. The location where image processing is performed, i.e., location of darkrooms, film storage area, location of CR cassettes, CR reader and computer workstations.
8. The position of all windows, doors, louvers, etc.
9. The planned and existing materials used to construct the walls, floor, and ceiling, and their thicknesses including additional materials currently being used, or planned for use, as radiation shielding barriers.
10. The application of protective barriers capable of attenuating the primary beam or secondary radiation according to the X-ray beam orientation.

#### **B.1.2.2. Considerations for Room Design and Layout**

When designing the layout of the X-ray facility, the following general recommendations must be considered.

1. Transportable X-ray equipment used routinely in one location must be considered as a fixed installation and the shielding needs for the equipment and room must be determined accordingly.

2. Rooms containing X-ray equipment must be designed so that the operator is not exposed to the primary radiation beam and can keep a distance of at least 2 metres from the X-ray tube and from the patient during an irradiation. For CBCT devices, a distance of 2 metres with no shielding is not sufficient, and shielding requirements must always be assessed ( See Section B.1.3). If it is not possible for the operator to keep the required distance from the X-ray tube, an adequately shielded barrier, which allows observation of the patient, must be provided for the operator to stand behind during an irradiation.
3. The location of an installed irradiation switch must be behind a protective barrier (Adequate according to Sections B.1.2.3 and B.1.3) or at least 2 metres from the X-ray tube and from the patient. For CBCT X-ray devices, shielding requirements must always be assessed (refer to Section B.1.3). Distance alone without intercepting shielding is typically not sufficient due to the increased scatter radiation<sup>7,8</sup> that is produced from CBCT exposures.
4. The irradiation control switch must be installed so that the operator can monitor the passage of members of the public who may be exposed by the secondary radiation.
5. For patient safety and to ensure patient has not moved prior to imaging, the operator must be able to observe the patient during a panoramic or CBCT exposure. This may be achieved using an appropriately shielded window, camera/monitor, a mirror, or other means of viewing the patient.
6. The rooms containing the X-ray equipment should be designed to provide adequate working space to the equipment operator and to allow for ease of patient movement.
7. The X-ray equipment must be positioned in the room in such a way that, during an irradiation, no one can enter the room without the knowledge of the equipment operator.
8. The X-ray beam must always be directed toward adequately shielded areas.
9. Shielding must be constructed to form an unbroken barrier and if lead is used it should be adequately supported to prevent creeping (deformation).

#### **B.1.2.3. Determination of Parameters Governing Structural Shielding Requirements**

The thickness of the shielding material, such as lead, concrete, or gypsum wallboard, required to reduce radiation levels to the recommended dose limits or lower can be determined through calculations. In general, the radiation exposure to individuals depends primarily on the amount of radiation produced by the source, the distance between the exposed person and the source of the radiation, the amount of time that an individual spends in the irradiated area, and the amount of protective shielding between the individual and the radiation source.

For all types of dental X-ray equipment, an expert in radiation protection must be consulted to ensure that the level of radiation safety of the facility is adequate. Given that dental radiography is performed at relatively low doses, dental facilities where the radiological workload is low may not need shielding in addition to the level of protection provided by typical

gypsum wallboard construction. Special consideration must be given to radiation protection when using CBCT, transportable or mobile dental X-ray equipment.

The parameters listed below must be considered for the calculation of barrier thicknesses. Allowance should be made for possible future changes in any one or all of these parameters, including increases in use and occupancy factors, in operating tube voltage and workload, as well as modifications in techniques that may require ancillary equipment.

#### 1. The Maximum X-ray Workload (W)

The workload is a measure of the operational time or the amount of use of the X-ray equipment. The workload can be determined by recording the current-time product of each irradiation taken for each dental X-ray device over a set period of time (i.e., week). If actual workload values are not available, estimated total workloads for various dental X-ray equipment are available in references<sup>17</sup>.

#### 2. The Occupancy Factor (T)

The occupancy factor is the fraction of time that the area under consideration is occupied by the individual (employee or public) who spends the most time at that location while the X-ray equipment is operating. If occupancy factors cannot be readily estimated, typical factors are available from references<sup>17</sup>.

#### 3. The Use Factor (U)

The use factor is the fraction of the workload during which the X-ray beam is pointed in the direction under consideration. If use factors cannot be readily estimated, typical factors are available from references<sup>37</sup>.

#### 4. Shielding Design Goal (P)

The shielding design goal is the air kerma value used in shielding calculations to ensure that exposure levels for persons in controlled and uncontrolled areas are lower than or meet exposure limits. The shielding design goals for facilities with dental X-ray equipment should be one of the following in controlled areas:

- (1) 1 mGy/y wherever practical and reasonably achievable, and where as per Section A.2.1, item 10, personal dosimeters would not be required after consideration of the results of the facility radiation survey conducted by an expert in radiation protection (See Section B.5.0), or
- (2) 5 mGy/y, where as per Section A.2.1, item 10, personnel must wear a personal dosimeter for the first year of operation until a baseline annual radiation dose is established. After review of the first annual radiation dose (In consultation with an expert in radiation protection as needed), along with consideration of any potential variation in factors

contributing to future radiation dose, if the dose is expected to be below 1 mSv/y the use of a personal dosimeter can be discontinued.

The shielding design goal for uncontrolled areas should be 1 mGy/y.

Provinces and territories may have specific requirements for shielding design goals. Facilities that fall under provincial or territorial jurisdiction should consult the regulatory authority listed in Appendix I for their respective region to obtain detailed information on any provincial or territorial statutory or regulatory requirements.

### **B.1.3. Shielding Calculations**

In dental facilities, shielding calculations must be made for both primary and secondary protective barriers. Primary protective barriers provide shielding from the direct X-ray beam and therefore must be placed in such an orientation as to intersect the X-ray beam. Secondary protective barriers are required to provide shielding from scattered and leakage X-rays.

Comprehensive shielding calculations for dental facilities should only be performed by individuals with current expertise in structural shielding design and the acceptable methods of performing these calculations. It is recommended that shielding calculations be performed using the methodology presented in the National Council on Radiation Protection Measurements Report No. 145: Radiation Protection in Dentistry<sup>37</sup>. Note that shielding values should always be calculated, rather than using the values listed in the table in appendix F of NCRP Report No. 145. While NCRP Report No. 177 was published in 2019 and supersedes NCRP Report No. 145, this Safety Code recommends the shielding calculations methodology of NCRP Report No. 145 be used as it includes primary shielding considerations for intra-oral dental X-ray devices which will offer more comprehensive protection.

The information outlined in Section B.1.2 along with the final plans of the installation must be submitted to the appropriate responsible government regulatory authority for review as required. Radiological facilities that fall under provincial or territorial jurisdiction should contact the responsible regulatory authority in their respective province or territory listed in Appendix I.

#### **B.1.3.1. Shielding of Radiographic Films and CR Cassettes**

Film storage containers must be adequately shielded to ensure that excessive exposure of film by X-rays does not occur. Sufficient film shielding as needed must be in place to reduce the radiation level to stored film to less than 1.75 µGy over the storage period of the film. Once films are loaded into cassettes, radiation exposure levels should be less than 0.5 µGy and the resulting increase in the base-plus-fog should be less than 0.05 O.D. Given that CR Cassettes are used more frequently and therefore stored for shorter periods of time, the limit of 0.5 µGy is also considered to provide sufficient shielding for CR cassettes.

### **B.1.3.2. Intra-oral Dental X-ray Equipment**

Primary and secondary shielding must be addressed for intra-oral dental X-ray equipment for which the X-ray tube can be manipulated in several directions. The walls where the X-ray tube can be directed are considered primary barriers, whereas the other walls, ceiling, and usually the floor are secondary barriers. If the patient is fully reclined and the X-ray tube is directed to the floor, then the floor becomes a primary barrier. If there is more than one dental chair in the room, shielding considerations must take into account the protection of patients and personnel from dental X-ray equipment used at both of the dental chairs.

Shielding calculations are not generally performed for hand-held dental X-ray equipment operated in a temporary location. Consequently, strict adherence to other protective measures, including a distance of at least 2m between the hand-held X-ray device and all persons other than the operator and patient, is necessary to avoid unintentional radiation exposure to personnel and the public. To ensure appropriate radiation protection, a controlled area where imaging is conducted must be established and access restricted.

### **B.1.3.3. Extra-oral Dental X-ray Equipment**

Extra-oral dental X-ray equipment generally has primary shielding behind the image receptor, meaning facility shielding only needs to address the secondary radiation. Due to differences in radiation output, the shielding requirements of panoramic and CBCT dental X-ray equipment cannot be assumed to be equivalent, and should be treated separately.

## **B.2.0. Dental X-ray Equipment Requirements**

### **B.2.1. Regulatory Requirements for Dental X-ray Equipment**

All new, used and refurbished dental X-ray equipment, and accessories for such equipment, which are sold, imported or distributed in Canada, must conform to the requirements of the *Radiation Emitting Devices Act* and the *Food and Drugs Act* and their promulgated regulations, which are the *Radiation Emitting Devices Regulations* and the *Medical Devices Regulations*. The *Radiation Emitting Devices Regulations*, Schedule II, Part II – Dental X-ray Equipment<sup>38</sup> sets out the requirements for information and labelling, construction and performance of dental X-ray equipment, with respect to radiation safety. The *Medical Devices Regulations* set out requirements for device safety, quality and effectiveness including device licensing. It is the responsibility of manufacturers, distributors and importers to ensure that their equipment complies with these regulations prior to importation and/or sale in Canada. Regulatory requirements should be reviewed during acceptance testing to ensure all device radiation safety, quality and effectiveness requirements are met. Dental facilities under provincial or territorial jurisdiction may be subject to additional requirements specified under their statutes and regulations.

*The Radiation Emitting Devices Act*, the *Food and Drugs Act* and their promulgated regulations are available on the Government of Canada Justice Laws website (<http://laws-lois.justice.gc.ca/eng/acts/>)<sup>39</sup>.

### **B.2.2. Equipment Purchasing**

When purchasing dental X-ray equipment, a needs analysis should be performed to identify the appropriate type and specifications of equipment required to meet the clinical X-ray imaging needs. The following points should be considered: the types of investigations that the facility intends to perform with the equipment, the level of performance needed from the equipment, whether the dental staff of the facility possesses the expertise to use the equipment, whether adequate space is available for installation of the new equipment, the electrical capabilities of the facility with respect to equipment requirements, and the date on which equipment must be installed and operational at the facility.

The need for additional equipment should be determined in advance and these items should be purchased at the same time as the X-ray equipment. This may include patient protective equipment (such as thyroid shields), personnel monitoring equipment (such as personal dosimeters), and testing equipment required to perform daily and monthly quality control procedures (such as specific test tools or phantoms).

### **B.2.3. Acceptance Testing**

Acceptance testing must be performed prior to any clinical use of the X-ray equipment. Acceptance testing is a process to verify compliance with the performance specifications of the X-ray equipment and that the equipment performance complies with federal and provincial or territorial regulations. For clarification regarding regulatory requirements, contact the applicable regulatory authority listed in Appendix I. The results from the acceptance testing should be used to set baseline values and acceptance limits on operational performance of the X-ray equipment. It is recommended that acceptance testing be performed by an expert with in-depth knowledge of the X-ray equipment, relevant regulations and radiation protection principles. The owner may consider having the acceptance testing performed by a person or organization who is independent of the manufacturer.

A detailed description of the acceptance testing is provided in Section C.2.0.

### **B.2.4. Existing Dental X-ray Equipment**

It should be noted that under the *Radiation Emitting Devices Act* the definition of a radiation emitting device includes “any component of or accessory to a device” that is capable of producing and emitting radiation. Replacements for any component or subassembly of dental X-ray equipment for which a construction or performance standard has been specified in the regulations must comply with the standard. In addition, upgraded components and/or software



must be licensed by Health Canada. For replacement components, as well as resale of dental X-ray equipment, devices and components that are manufactured after May 15, 2018 are subject to the current dental X-ray equipment standard of the *Radiation Emitting Devices Regulations*. Devices and components manufactured prior to May 15, 2018 are subject to the standard as it read immediately before that date. Current and previous versions of the *Radiation Emitting Devices Regulations* are available on the Government of Canada Justice Laws website. Information on licensing of dental X-ray equipment, accessories or software is available from the Medical Devices Directorate of Health Canada (contact information available in Appendix I). The owner of a dental facility must ensure that any upgrades or changes to the equipment or software meet all applicable federal, provincial and territorial requirements. For clarification regarding regulatory requirements, contact the applicable regulatory authority listed in Appendix I. Any changes or upgrades of equipment affecting image quality and/or radiation dose must undergo acceptance testing.

### **B.2.5. Retrofitting with Digital Imaging Systems**

When retrofitting a digital image receptor (e.g. Digital Radiography (DR) or Computed Radiography (CR) system) into a new or existing dental X-ray system, the owner of the facility must ensure that the digital image receptor meets the requirements of the *Radiation Emitting Devices Act and Regulations*, as well as the *Food and Drugs Act* and the *Medical Devices Regulations*. The system must be calibrated to reflect the sensitivity of the digital image receptor, and the system must be capable of sufficiently short exposure time settings for optimized exposure of the digital image receptor. For intra-oral dental X-ray equipment, all anatomical presettings must be adjusted to optimize for the digital image receptor, in order to minimize patient dose. The adjustments should be done by the vendor or dental service provider through which the device was purchased, or by an expert in radiation protection.

### **B.3.0. Imaging Processing Systems**

Image processing includes both film and digital processing of radiological images. Film processing systems have been extensively used in the past. Recently, with advances in digital technology, digital image processing systems are being used in many dental facilities. No matter the type of system used, optimization of image quality at an acceptable dose to the patient is a priority for dental facilities. This is achieved by ensuring image processing is an integral component of the facility's quality assurance program.

#### **B.3.1. Film-Based Systems**

The ability to produce a radiograph of satisfactory diagnostic quality at an acceptable dose to the patient depends on the technique used when performing the examination, the appropriate selection of loading factors, the film-screen employed, the handling and processing of the film,



and on the conditions of viewing the image. Good image quality requires proper darkroom techniques, routine processor quality control monitoring, and careful adherence to film and processor manufacturers' instructions.

#### **B.3.1.1. X-ray Film**

X-ray films are sensitive to light, heat, humidity, chemical contamination, mechanical stress and X-radiation. Unexposed film must be stored in such a manner that it is protected from stray radiation, chemical fumes and light. Generally, X-ray films should be stored on edge, in an area away from chemical fumes, at temperatures in the range of 10°C to 21°C and humidity between 30% and 60%. The film manufacturers' instructions must be followed. Sealed film packages must be allowed to reach room temperature before opening to prevent condensation on the films. Radiation exposures to stored film must be limited to 1.75 µGy for the entire storage period of the film. Loaded cassettes must be stored in an area shielded from exposure to radiation; this area is usually in or near the X-ray room. Films should never be left inside cassettes with screens for any extended period of time. For panoramic dental X-ray equipment, the location of loaded and unexposed cassettes must be clearly marked. X-ray film past its expiry date should be discarded.

#### **B.3.1.2. Cassette and Screen**

Facilities operating panoramic or cephalometric X-ray equipment may use film cassettes with screens as part of the image receptor. Cassettes or screens in poor condition will impair diagnostic quality. Problems are caused by dirty or damaged screens, warped cassettes, fatigue of foam, compression material or closure mechanism, light leaks, and poor film-screen contact. Cassettes should be checked regularly for wear and cleanliness and any damaged cassettes should be replaced. Manufacturers' recommended screen cleaner should be used. To avoid artifacts caused by dirt and dust, the intensifying screens and cassettes should be cleaned at least monthly.

#### **B.3.1.3. Darkroom**

Manual processing of films requires the use of a proper, well-equipped darkroom. Automatic film processors also require properly designed darkrooms, with the exception of daylight loaders on automatic image processors. While specific details may vary from installation to installation, all darkrooms must include the following basic features:

1. The room must be light-tight (See Section C.3.2 item M3). Particular attention must be paid to the door seal and the mounting of the film processor if the film insertion to the processor is done through a wall. The darkroom should incorporate a lockable door or double doors to ensure light-tightness when undeveloped films are being handled.
2. If the darkroom is adjacent to an X-ray room, the film storage container must be adequately shielded to ensure that excessive exposure of film by X-rays does not occur. Sufficient film

shielding must be in place to reduce the radiation level to the film to 1.75  $\mu\text{Gy}$  for the storage period and to the loaded cassettes to 0.5  $\mu\text{Gy}$ .

3. A warning light should be located outside the darkroom, at the entrance, to indicate when the room is in use. The warning light is not required if the door is locked when it is closed.
4. Safelights, fitted with bulbs of intensity not greater than 15 watts, must be provided above the work areas inside the darkroom. The safelight must have filters (GBX 2 or equivalent) appropriate to the specifications of the film used and must be positioned at distances greater than 1 metre from work areas to minimize film fogging. Safelight filters should be checked regularly since they may deteriorate with time or may crack.
5. For manual processing, the darkroom must be equipped with proper stainless steel processing tanks with water bath and lids, including an accurate thermometer and timing device.

#### **B.3.1.4. Cleanliness**

Cleanliness in the darkroom and of the screens and cassettes is essential. It is important to maintain the cleanest environment possible in order to minimize any artifacts caused by dirt, dust, or improper handling of film.

1. Eating or drinking in the darkroom area must not be permitted.
2. All working surfaces, tops of counters and the floor should be cleaned regularly, at least once a day.
3. Tops of cabinets, vents, light fixtures and any other areas which can collect dust should be cleaned on a regular basis.
4. The ventilation system should be checked to make sure that no dust is carried from it to the inside of the darkroom; any filter should be changed on a regular basis.

#### **B.3.1.5. Handling of Film**

1. To avoid putting fingerprints on the film and to avoid dirtying the screens, it is important to wash hands frequently with soap that does not leave any residue.
2. The use of hand lotions and creams may also result in fingerprints on films and should be avoided.
3. Clutter which may collect dust should be eliminated.
4. Corrugated cardboard boxes containing film boxes, chemicals, and other supplies should not be stored or opened inside the darkroom.
5. The boxes should be opened outside the darkroom, and films and supplies carried inside.

6. Any articles of clothing made of loose fibres or which are static generating, such as wool, silk, some cottons or cotton blend fabrics, should not be worn in the darkroom or should be covered with a laboratory coat.

#### **B.3.1.6. Film Processing**

Improper or careless processing of exposed radiographic films can cause films of poor diagnostic quality and consequently result in an increased chance of a wrong diagnosis or the need for repeat exposures. With both manual and automatic processing, to achieve full development of a film which has been exposed using correct radiographic technique factors, the film must be processed in chemically fresh developer, at proper temperature and for sufficient time to ensure that the silver in exposed silver halide crystals in the film emulsion is completely reduced into black metallic silver. If this is not done, the blackening of the film will not be optimal and the tendency will be to increase radiation exposure to achieve proper image density. Other factors can also affect the quality of the processed film. These include cleanliness of the processing system, film immersion time, and agitation.

To ensure proper processing of films certain basic recommendations must be considered:

1. Manufacturers' instructions with respect to strength of solution, temperature and time must be followed to ensure optimum development.
2. Developing solutions must be changed regularly, as required.
3. Developing solutions must be monitored regularly. Even unused developer deteriorates with time. Developer must not be used when processing times become significantly longer than what is recommended by the manufacturers or the radiation dose necessary to obtain an acceptable film density has also increased significantly.
4. Cleanliness is extremely important for reducing film artifacts for both manual and automatic film processing. Proper processing tanks complete with water bath and lids should be used for manual processing. With automatic processors the film transport mechanisms should be cleaned frequently.
5. Automatic film processors must be maintained regularly, in accordance with the manufacturer's instructions. The temperature and composition of the processing chemicals must be kept within the specified tolerances. It should be noted that the performance of automatic processors can vary from day-to-day and therefore routine monitoring of the processors is important.
6. For automatic processors which have a daylight loader, the entry sleeves and box must be checked for tears or cracks as these may cause film fogging.

#### **B.3.1.7. Viewbox**

The conditions of viewboxes must be checked regularly along with the conditions under which dentists and other health care professionals examine radiographs since this may influence diagnostic accuracy. Problems with improper illumination due to the non-uniformity of fluorescent tubes or degradation and discolouration of the viewing surface must be corrected. It is best to use only one type of fluorescent tube within a facility. These tubes should be changed when signs of aging develop, such as flickering, inconsistent illumination or low light output. Care should be taken to clean the viewing surface of the viewbox such that no dirt could influence diagnostic accuracy.

### **B.3.2. Digital Imaging Systems**

Many Canadian dental facilities have transitioned from film-screen imaging to digital imaging. Various digital systems are available using different types of image receptor technologies to produce the digital images. In general, digital imaging equipment is categorized into two groups: Computed Radiography (CR) systems or Digital Radiography (DR) systems.

- CR systems consist of a CR imaging plate, which contains a photostimulable storage phosphor, and an imaging plate reader. Panoramic equipment also includes a cassette for the CR imaging plate. The CR cassette, loaded with an imaging plate, is positioned in the panoramic system as it is done with film cassettes. Upon X-ray exposure, the imaging plate stores the latent image. The imaging plate is then read by an imaging plate reader and a digital image is produced.
- DR systems consist of an image receptor that converts the X-ray signal into an electronic signal carrying the image information, which is processed and displayed almost instantaneously. For intra-oral equipment, the DR image receptor is positioned in the patient's mouth the same as it is done with film.

Quality control testing of digital image systems is essential. Verification of proper functionality of the X-ray imaging equipment along with appropriate selection of technique and loading factors remains essential for obtaining a satisfactory image at a minimal dose to the patient. For digital systems, specific quality control testing must also be performed on the image acquisition, storage, communication and display systems. In Section C of this Safety Code, general quality control tests have been included for digital imaging systems. In addition to these tests, all equipment-specific, manufacturer-specified tests must also be performed.

#### **B.3.2.1. Computed Radiography Imaging Plates**

Computed radiography imaging plates are reusable and can be exposed, read and erased repeatedly. For this reason, it is necessary to evaluate the conditions of imaging plates on a regular basis. With normal use, the accumulation of dust, dirt, scratches and cracks may reduce image quality. Exposure to chemical agents, such as non-approved imaging plate cleaners,

handling with dirty or wet hands or contact with hand lotions are all possible causes of imaging plate damage. A log book should be maintained to track the physical conditions of all imaging plates and cassette assemblies. The cleaning frequency depends on patient volume, plate handling, and the frequency at which artifacts are perceived. When significant artifacts are visible in the image, plates need to be discarded. Significant artifacts detrimentally impact the diagnostic quality of the image and may lead to unnecessary retakes. In general, a weekly visual inspection for dust and dirt is recommended. The imaging plates must be cleaned monthly following manufacturer recommended procedures and using manufacturer recommended cleaners. Cleaner must not be poured directly onto the plates as this may cause staining.

#### **B.3.2.2. CR Cassette**

Under normal conditions of use, dust and dirt can accumulate on cassettes. A log book should be maintained to track the physical conditions of all cassettes. In general, a weekly visual inspection for dust and dirt should be done. Monthly cleaning of CR cassettes following manufacturer recommended procedures and using manufacturer recommended cleaners must be done (See Section C.3.2, item M1).

When not in use, CR cassettes, loaded with an imaging plate, must be stored in a closed container that blocks out ambient light and such that the level of radiation exposures is limited to 0.5  $\mu$ Gy for the storage period.

#### **B.3.2.3. Intra-oral CR and DR image receptors**

Intra-oral image receptors must be cleaned and disinfected after each patient use. Manufacturer recommended cleaners and cleaning procedures should be used. Also note that, while beyond the scope of this Safety Code, regulatory authorities may have infection prevention and control requirements applicable to disinfecting image receptors. Intra-oral CR and DR image receptors may deteriorate over time due to extensive handling and positioning within the mouth, therefore these receptors must be regularly inspected for damage, including wear, warping, dents and cracks that may result in image artifacts. When significant artifacts are visible in the image, receptors need to be discarded. Significant artifacts detrimentally impact the diagnostic quality of the image and may lead to unnecessary retakes. The cable on DR image receptors must also be checked regularly for damage (e.g. fraying) that may prevent acquisition of the image data. If a cord is damaged, the receptor must not be used until the damaged cords are replaced. Damaged cords may lead to unnecessary retakes due to failure of the image receptor.

#### **B.3.2.4. Electronic Display Devices**

The performance of electronic display devices must be checked routinely. Monthly verification of the display must be performed using test patterns designed for evaluating various characteristics of display performance<sup>40,41</sup> (See Section C.3.2, item M7). A detailed annual evaluation should be performed by a expert with knowledge in electronic display device testing.

The cleanliness of the display surface must be maintained and basic functionality should be confirmed (power on/off, visible display). Manufacturer recommended cleaners and cleaning procedures must be followed. Section C.3.3, item A16 of this document provides a description of these quality control tests. Attention must be given to reading room viewing conditions when performing quality control tests of display monitors.

#### **B.3.2.5. Imaging Software**

There are many options for image processing available across various imaging software, ranging from standard image enhancement options (e.g. window and levelling, edge enhancement), to implant planning software for CBCT equipment as well as the possibility of adding a management system that can maintain an exposure registry for repeat analysis. The capabilities of the imaging software used to display dental radiographs must suitably address the specific clinical needs of the facility. Image processing software should also ensure preservation of the original image data, such that after image processing options have been applied the unprocessed image can still be viewed. The imaging software should not allow diagnostically inadequate images to be immediately deleted, so that reject/retake analysis of the inadequate image can be done during quality control.

#### **B.3.2.6. Image Archiving System**

In digital imaging, a system must be in place to manage patient images so that secure storage and timely retrieval of images is possible. Attention must be given to ensure that the quality of patient images is maintained (i.e. uncompressed, original image data) and that patient information is not lost or unintentionally altered. Such situations can lead to repeat radiographic examinations and misdiagnoses for patients.

When deciding upon specifications of an image archiving system, the following key components should be considered:

1. Ensure that all practice management systems in the facility can be integrated as required. Information being transferred from one system to another will remove the need to re-enter information independently into each system and thus avoid inconsistencies, redundancies, and unavailability of data.
2. Security of patient information must be a priority. Only authorized individuals must be able to access patient data and images. Authorized system users must understand the importance of keeping system passwords confidential.
3. Image archiving system should be routinely backed up to prevent permanent loss of X-ray images.
4. When deciding upon the network and storage requirements of an imaging or information system it is important not to limit the systems to only the current needs of the facility. The

system should be scalable to allow for future growth of the system. The system capacity should be based upon the following points:

- (i) the current modalities from which studies are acquired;
- (ii) the average number of images per examination by modality;
- (iii) the number of pixels and bit depth of the image;
- (iv) number of examinations performed each year;
- (v) projected procedure growth volume;
- (vi) image file mobility including the ability for a client to take their X-ray images with them when changing dentists; and,
- (vii) modalities to be added in the future.

#### **B.3.2.7. Teleradiology**

Teleradiology is the electronic transmission of radiological images from one location to another for the purposes of interpretation and/or consultation. Through teleradiology, digital images and patient information can be accessed electronically from multiple sites simultaneously. The benefits of teleradiology include more efficient delivery of patient care and the ability to provide radiological services to facilities in remote areas which do not have image interpretation capabilities available on-site. Security of patient information must be a priority. Only authorized individuals must be able to access patient data and images. Authorized system users must understand the importance of keeping system passwords confidential.

Since teleradiology involves the acquisition and interpretation of patient images at different sites, it is important that policies and procedures be in place at all locations to ensure image quality is optimized and comparable among all facilities accessing patient images. This is especially important when official authenticated written interpretations are made through teleradiology.

Images sent by teleradiology must not be digitally compressed, as this will reduce the image quality. Images obtained through post processing of the original image must not be used to the exclusion of the original images themselves, as they must only be used to support the interpretation process. The relevant workstation quality control tests set out in Section C must be performed at the required frequencies for workstations used for interpretation of teleradiology images.

#### **B.4.0. Other Equipment**

Consideration must be given to other equipment, such as those used for personnel and patient protection, and equipment testing, which are necessary for ensuring the radiation safety of a

dental facility. Protective equipment must provide adequate protection without being unduly restrictive and heavy. All test equipment must be properly maintained and carefully stored.

#### **B.4.1. Protective Equipment**

1. Protective lead aprons and thyroid shields must provide sufficient protection in the voltage range of the X-ray tubes of the working environment. The attenuation equivalent of the protective equipment must be at least:
  - (i) 0.25 mm of lead, for a working environment where the peak X-ray tube voltage is 100 kV or less,
  - (ii) 0.35 mm of lead, for a working environment where the peak X-ray tube voltage is greater than 100 kV and less than 150 kV<sup>42</sup>
2. The lead equivalent thickness of the protective material used must be permanently and clearly marked on all protective equipment and apparel. The label must indicate the X-ray tube voltage at which the lead equivalence is determined, as the lead equivalence of composite and non-lead protective equipment can vary according to the X-ray tube voltage<sup>43,44</sup>. The methodology used to determine the lead equivalence should follow recognized standards such as IEC 61331-1:2014<sup>45</sup>.
3. All protective equipment must be tested on a yearly basis for integrity and results must be included in the quality control test records (See Section C.3.3, item A17).
4. Defective equipment must be removed from use.
5. Protective equipment must be stored and maintained according to manufacturers' instructions.

#### **B.4.2. Test Equipment**

1. All equipment used for acceptance and quality control testing must be evaluated for their functioning and performance on a regular basis.
2. All dose meters and tube voltage meters used to measure X-ray tube parameters should be calibrated on a regular basis according to manufacturers' recommendations.
3. All phantoms and other equipment used for the assessment of image quality, dose and system performance should be checked for damage or any condition which may affect their use.
4. Test equipment should be stored away from heat, direct sunlight, and high humidity, and must be operated following manufacturers' recommendations.



## B.5.0: Radiation Protection Surveys

A radiation protection survey is an evaluation of the radiation safety of a dental facility. The survey is intended to ensure compliance with the requirements of this Safety Code, to demonstrate that X-ray and auxiliary equipment function properly and according to applicable standards, and that the equipment is installed and used in a way which provides maximum radiation safety for operators, patients and others. As part of the radiation safety program for a facility, it is the responsibility of the owner to ensure that radiation protection surveys are conducted as indicated in Section B.5.1 below. Facilities under provincial or territorial jurisdiction may be subject to requirements under their statutes. The authorities listed in Appendix I should be contacted for details of the regulatory requirements of individual provinces and territories.

The regulatory authority may request reports of quality control performed at the facility during the investigation or once it has been completed. Safety measures such as protective equipment and shielding are also examined to ensure that they are present and provide the required protection. It is important, therefore, that X-ray facilities are surveyed at regular intervals.

### B.5.1. General Procedures

Routine operation of any new installation or an installation which has undergone modifications should be deferred until a complete survey has been made by an expert in radiation protection. These procedures include evaluation of the facility design to ensure adequate shielding is in place, inspection and evaluation of the performance of X-ray equipment and accessories, and evaluation and recommendation of radiation protection programs. The owner of the facility (or another delegated staff member) must contact the appropriate regulatory authority to ascertain inspection and acceptance testing procedures in that jurisdiction. Some jurisdictions may require that the facility be declared in compliance with applicable governmental regulations prior to operations. Provincial and territorial regulations and professional orders may also establish requirements relating to who can perform specific actions or roles outlined in this Safety Code, including some in this section. For clarification regarding regulatory requirements, contact the applicable regulatory authority listed in Appendix I.

For a new facility, it is particularly advantageous to perform visual inspections during the construction phase, to ensure compliance with design specifications and to identify faulty material or workmanship, since deficiencies can be remedied more economically at this stage than later. Such inspections should include determination of lead and/or concrete thickness and density, and degree of overlap between lead sheets or between lead and other barriers. Evidence/documentation of installation of the shielding should be retained as part of the facility's shielding records.

For existing installations, a survey must be carried out after any changes are made which might produce a radiation hazard. This includes alteration of protective barriers, equipment

modification and replacement, change in location or orientation of an X-ray device, structural changes to the room, changes in operating procedures, or increased workloads.

Finally, radiation protection surveys must be carried out at regularly scheduled intervals during routine operations to detect problems due to equipment failure or any long-term trends toward a decrease in the level of radiation safety. Facilities should contact the applicable regulatory authority to establish the survey schedule. If a survey frequency is not set by the responsible regulatory authority, surveys may be conducted every three years. For clarification regarding regulatory requirements, contact the applicable regulatory authority listed in Appendix I.

The results of such surveys, including conclusions drawn by the expert in radiation protection, must be submitted to the owner in a written report. All such reports must be retained by the owner. For federal facilities, radiation survey reports must be maintained for 5 years and personnel dosimetry records for the lifetime of the facility.

### **B.5.2. Survey Report**

The survey report must present, in a clear systematic way, the details and results of the measurements carried out, as well as the conclusions drawn and recommendations made by the surveyor. Any unusual findings about the equipment itself, the facility or operating procedures, which could affect the safety of operators or other persons in the vicinity of the X-ray facility, must be clearly identified.

The survey report must include the following:

1. a sketch or photo of the facility, showing the location of the X-ray equipment and control panel within the facility as well as the nature and occupancy of the area adjoining the facility;
2. identification of the dental X-ray equipment (i.e., the name of the manufacturer, model designation and serial number of the generator, control, X-ray tube assembly, etc. as applicable) and the date, or at least the approximate date manufactured;
3. observations of the operational conditions (both electrical and mechanical) of the X-ray equipment at the time of the survey;
4. the actual or estimated total workload of the facility, as well as the workload apportioned into various X-ray beam directions and procedures used;
5. results of radiation measurements carried out both inside and outside the controlled area under "typical" operating conditions;
6. the locations at which the measurements are made;
7. an assessment of the condition of protective aprons and other protective devices;

8. an estimate of potential exposures to personnel and general public in or around the facility;
9. an evaluation of the X-ray performance and the imaging or diagnostic performance (this may include performing applicable quality control tests from Sections C3.1 to C3.3);
10. a summary of typical loading factors used and a measurement of the total filtration in the X-ray beam;
11. an assessment of radiological techniques from the point of view of radiation safety and an assessment of the DRLs for the facility. Attention must be drawn to any practices which are or could be detrimental to the patient or to personnel working in the facility. Recommendations of improved or safer techniques should be made in such cases;
12. a review of the facility's quality assurance program to ensure it exists and is maintained, including quality control testing records;
13. the methodology and test instruments used for the survey; and
14. recommendations regarding the need for a follow-up survey.

### **B.6.0: Disposal of Dental X-ray Equipment**

When X-ray equipment is considered for disposal, an assessment should be made as to whether the equipment can be refurbished and/or recycled. Communication with the manufacturer or supplier of the equipment should be made as to whether the equipment or components of the equipment can be recycled or returned. Once the decision has been made to dispose of X-ray equipment, an assessment must be made to determine if any equipment components contain hazardous materials.

An assessment should include the following:

1. Contact the manufacturer or supplier of the equipment to determine if the equipment or components of the equipment can be recycled or returned.
2. If the equipment contains any patient information, this information must be fully removed.

It is strongly recommended that disposal of X-ray equipment be delegated to an X-ray service provider that specializes in the disposal of such systems. Safe work practices during disposal must be used so that workers are not exposed to hazards.

The following disposal actions are recommended:

1. The X-ray tube window should be examined to determine whether or not it contains beryllium, and if it does, special disposal procedures must be applied since beryllium presents a toxic ingestion or inhalation hazard;

2. The transformer oil must be disposed of in accordance with any applicable federal, provincial or territorial environmental legislation and lead must be recycled accordingly;
3. To ensure that the equipment is not unsafely operated after disposal, the equipment must be made inoperable before disposing. The vacuum in the X-ray tube must be breached, and the cables that power the equipment and other electrical connections should be disconnected and disposed of separately.

It is recommended that dental facilities under provincial or territorial jurisdiction contact the responsible regulatory authority in their respective province or territory for further information. A listing of these responsible regulatory authorities is provided in Appendix I.

## Section C: Quality Assurance Program

### C.1.0. Introduction

All dental facilities must develop and maintain an effective quality assurance program. In dental radiography, a quality assurance program is defined as the planned and organised actions necessary to provide adequate confidence that dental X-ray equipment and related components reliably produce quality radiographs with minimum doses to patients and staff. A Quality Assurance program includes quality control procedures for the monitoring and testing of dental X-ray equipment and related components, and administrative procedures to ensure that monitoring, evaluation and corrective actions are properly performed. The owner of a dental facility has the responsibility of establishing a quality assurance program that examines all practices of the facility which affect:

1. *Information Quality* – ensure all diagnostic information produced provides for accurate clinical assessment;
2. *Clinical Efficiency* – ensure all steps leading to accurate diagnosis and intervention are taken and the information is made available in a timely fashion to the patient's dentist or primary dental professional; and
3. *Dose* – ensure the radiographic examination is performed with the lowest possible radiation dose to the patient, staff and others consistent with clinical imaging requirements.

### C.1.1. Goals of the Quality Assurance Program

The ultimate goal of a quality assurance program is to ensure accurate and timely diagnosis at the minimum dose to the patient and staff. In order to have a successful quality assurance program it is essential that equipment is in proper working condition and all staff members understand the goals of the program and are committed to the implementation of the program through full participation.

Any program initiated only to comply with regulatory requirements is not likely to provide maximum possible benefit to the patient. It is, therefore, essential that all dental staff understand, support and participate in the operation of the quality assurance program. Some provincial/territorial jurisdictions require facilities to implement and participate in a quality assurance program. For clarification regarding regulatory requirements, contact the applicable regulatory authority listed in Appendix I.

Information obtained from dental X-ray equipment must be of highest quality to ensure accurate diagnosis and treatment. If critical elements are missing or image artifacts are present, the image is considered to be of poor quality. The consequence of poor quality diagnostic

information may be incorrect diagnosis resulting in repeat X-ray procedures, unnecessary radiation doses to the patient and operator, delayed or improper patient treatment and increased cost.

### C.1.2. Implementation of Quality Assurance Program

The implementation of a quality assurance program need not be complicated. It consists of establishing quality control procedures for the equipment along with an administrative methodology to ensure that monitoring, evaluation and corrective actions are properly performed.

#### C.1.2.1. Establishment of Quality Control Procedures

The following four steps must be included for the establishment of quality control procedures:

1. *Equipment operation* – It is essential that the dental X-ray equipment and image processing and display equipment function properly before a quality assurance program is implemented. Manufacturers and vendors should provide proper operating characteristics for their equipment. For film-based systems, films and processing must meet manufacturers' speed and contrast values. For CR and DR systems, the imaging system must be properly calibrated with the X-ray systems. This may involve replacement, repair, upgrading or calibration of the equipment.
2. *Baseline performance* – Baseline performance values of X-ray equipment and image processing system must be established after verifying that the equipment functions properly. This baseline performance will be used to diagnose any changes in equipment performance. It is important to keep records of equipment operation data and baseline performance measurements. These records will be needed to diagnose any changes in image quality. Baselines values must be determined when new equipment is introduced into the facility, when there are changes in components which affect image quality and patient dose and also when testing equipment is changed.
3. *Reference test image* – To evaluate image quality a reference test image is needed. This reference test image is made by using the X-ray equipment, image processing system and a quality control phantom and will be used for comparison of quality control test images.
4. *Result Evaluation and Action Levels* – An effective quality control monitoring program includes not only a routine quality control testing schedule, data recording and record keeping, but also test result evaluation, such as determination of acceptable or unacceptable limits of equipment operation coupled with a list of corrective actions that may be required. A set of limits should be established which indicates a level of operation outside of which the system or the function should be closely monitored but where no immediate action is required. Another set of limits should also be established where immediate remedial action must be taken.

Many dental X-ray equipment supply companies distribute quality assurance kits which include test equipment to perform quality control tests and record keeping forms. Such kits may be useful in setting up quality assurance programs.

#### **C.1.2.2. Establishment of Administrative Procedures**

The following administrative procedures must be included in the establishment of an effective quality assurance program:

1. *Responsibility* – Although the owner of the dental facility is ultimately responsible for the implementation and operation of the quality assurance program, to obtain the optimal level of radiation safety and quality diagnostic information, it is imperative that full cooperation exists among all concerned parties. Staff members may be assigned duties with regard to equipment monitoring, record keeping and general operations of the quality assurance program. It is essential that the level of responsibilities and involvement of the owner and staff be clearly identified, communicated and understood.
2. *Record keeping* – It is essential that measurements and information gathered for the quality assurance program is clearly documented and readily available for evaluation. As much as practicable, recorded data should be indicated as data points on a control chart for each day the measurement is made. For example, it includes the quality control of dental film development (e.g. stepwedge ), and the charting of temperature for the film processor. In this form, trends can be easily detected. A log book or other easily identifiable method of recording should be used.

Some provincial or territorial jurisdictions may have different requirements for record keeping. The appropriate regulatory authority, listed in Appendix I, should be consulted to determine the requirements in effect in a particular jurisdiction.

3. *Evaluation of data* – Recorded data should be evaluated immediately and necessary actions taken expeditiously.
4. *Limits of acceptability of data* – Upper and lower limits of acceptability of recorded data must be determined and documented. When these limits are reached, corrective actions must be taken. For example, they can be the range of acceptable temperatures for the film processor. These limits should be set such that they are just within the range allowable before diagnostically significant image changes are evident. They should not be so restrictive that they exceed the capability of the equipment, or that frequent corrective actions are taken without any evidence of problems. These limits should be reviewed from time to time, especially when major components of the X-ray system are replaced or repaired.
5. *Testing Frequency* – Testing frequency must be such that a balance is reached between the cost of testing, disruption to the operation of the facility and the maintenance of quality. The frequency of testing should be increased if the equipment exhibits significant changes

between scheduled quality control tests, or if the equipment is used for exceptionally high volume of procedures. Additional testing should be performed if the results of testing fall outside of limits of acceptability for the tests, or after any corrective actions are made. Equipment must be retested after service to any part which may affect the image density, image quality or radiation output from the X-ray tube. The quality control program should not be discontinued if the results indicate relatively stable equipment performance. The purpose of a quality control program is to control quality, and periodic measurement of equipment performance is essential. Where there are differences between the manufacturer's recommended testing and the requirements of applicable legislation or policies, the more strict testing frequency should be followed to ensure compliance with legislation/policies and also to ensure fulfilment of equipment warrantee conditions of the manufacturer.

6. *Corrective actions* – There must be established repair and calibration procedures to deal with significant problems. A decision tree system should be developed to provide guidance to deal with events such as equipment failure and to deal with circumstances when equipment performance deviates beyond the set limits. A list of individuals having the authority to stop operation of an X-ray unit should be established. The decision tree should include the following steps:
  - (i) repeat the test to confirm;
  - (ii) what to do if repeated test confirms performance failure;
  - (iii) what to do if test fails only marginally;
  - (iv) what to do if test shows a history of failure; and
  - (v) what to do if test fails substantially.

### C.2.0. Acceptance Testing

Acceptance testing is a process to verify compliance with the performance specifications of the X-ray equipment and that the equipment performance complies with federal and provincial or territorial regulations. Acceptance testing must be performed prior to any clinical use of the equipment. It is recommended that acceptance testing be performed by an expert with in-depth knowledge of the X-ray equipment, relevant regulations and radiation protection principles. The owner may want the acceptance test to be performed by a person or organization who is independent of the manufacturer.

Acceptance testing of a dental X-ray system includes several major steps:

1. the verification that delivered components or systems correspond to what was ordered;



2. the verification of the system mechanical integrity and stability, including safety mechanisms, emergency stop system, power drives, and interlocks;
3. the verification that appropriate inspections of electrical installations have been carried out, including electrical safety and line power fluctuation;
4. the verification of X-ray performance; and
5. the verification of imaging or diagnostic performance.

Regulatory requirements should be reviewed during acceptance testing to ensure all requirements for device radiation safety, quality and effectiveness are met (See Section B.2.1).

The results from the acceptance testing should be used to set baseline values and acceptance limits on operational performance of the X-ray equipment. These baseline values and limits are essential to the quality assurance program.

### C.2.1. Acceptance Testing Evaluation

Acceptance testing for dental X-ray equipment should evaluate at least the items listed in Table 2. Not all equipment will be subject to the full set of tests. The type of equipment and its configuration will dictate the sets of tests to be performed. More detailed information on acceptance testing on dental X-ray equipment, including specifications for phantoms, is available from the International Electrotechnical Commission (IEC) for traditional devices<sup>46</sup> and cone beam CT<sup>47</sup>, as well as the European Commission<sup>8,16</sup>.

Appropriate loading factors that optimize the radiation dose while maintaining sufficient diagnostic image quality must be established for all imaging techniques used. For techniques that are set manually, a techniques chart must be affixed on or near the control panel. The loading factors for all preset techniques, where the techniques are selectable by anatomical indications (e.g. for “adult” and “bitewing”), must be optimized based on the results of acceptance testing, with the presets on the devices adjusted as required. It should not be assumed that the manufacturer recommended settings for preset techniques will provide optimized radiation doses for a given specific installation of a dental X-ray device.

**Table 2. Acceptance Tests**

Items Under Evaluation for Acceptance Testing	Intra-oral System		Panoramic System		Cephalometric System		CBCT System
	Film-based	CR or DR	Film-based	CR or DR	Film-based	CR or DR	
1.0 Identification							
1.1 Initial Inspection and inventory	X	X	X	X	X	X	X
1.2 Inspection of Documentation	X	X	X	X	X	X	X
2.0 Visual and Functional Tests							
2.1 Mechanical Properties	X	X	X	X	X	X	X
2.2 Safety Systems	X	X	X	X	X	X	X
3.0 Performance Evaluation (X-ray Generator)							
3.1 X-ray Tube Voltage	X	X	X	X	X	X	X
3.2 Current Time Product	X	X	X	X	X	X	X
3.3 Loading Time	X	X	X	X	X	X	X
3.4 Automatic Exposure Control	X	X	X	X	X	X	X
3.5 X-ray Beam Filtration	X	X	X	X	X	X	X
3.6 X-ray Beam Limitation and Alignment	X	X	X	X	X	X	X
3.7 Focal Spot to Skin Distance	X	X	X	X	X	X	X
3.8 Radiation Output	X	X	X	X	X	X	X

Items Under Evaluation for Acceptance Testing	Intra-oral System		Panoramic System		Cephalometric System		CBCT System
	Film-based	CR or DR	Film-based	CR or DR	Film-based	CR or DR	
3.9 Leakage Radiation	X	X	X	X	X	X	X
3.10 Dosimetric Indicator Accuracy	X	X	X	X	X	X	X
<b>4.0 Performance Evaluation (Image Receptor)</b>							
4.1 Spatial Resolution	X	X	X	X	X	X	X
4.2 Contrast Detectability	X	X	X	X	X	X	X
4.3 Film Cassettes/Screens			X	X (CR only)	X	X (CR only)	
4.4 Patient Positioning Indicators			X	X			X
4.5 Focal Trough Alignment			X	X			
4.6 Mean Voxel Values (calibration and linearity)							X
4.7 Uniformity		X		X		X	X
4.8 Artifacts	X	X	X	X	X	X	X
4.9 Noise		X		X		X	X
4.10 Modulation Transfer Function							X
4.11 Geometric Accuracy							X

\* CR: Computed Radiography, DR: Digital Radiography, CBCT: Cone Beam Computed Tomography

### C.3.0. Quality Control Testing Procedures and Equipment

Quality control testing must be carried out during routine operation of a dental facility. This section sets out the required and recommended quality control tests, the associated test equipment and testing frequencies. More detailed information on quality control testing on dental X-ray equipment, including specifications for phantoms, is available from the International Electrotechnical Commission (IEC) for traditional devices<sup>46</sup> and cone beam CT<sup>47</sup>, as well as the European Commission<sup>8,16</sup>.

Quality control testing of a dental X-ray system includes several major steps:

1. the verification of the system mechanical integrity and stability, including safety mechanisms, power drives, interlocks;
2. the verification of the performance of ancillary equipment such as imaging processors and display units;
3. the verification of X-ray performance; and
4. the verification of imaging or diagnostic performance, including assessments of dose.

Test equipment required for these tests must be readily available to the individuals responsible for performing these tests. All test equipment must be calibrated and verified to be operating accurately according to the frequency determined by manufacturer. Individuals performing quality control tests must be trained in the proper operation of the test equipment and in performing the tests.

In the following sections, the descriptions of each test indicate whether performance of the test is required or recommended. In addition, not all equipment will be subject to the full set of tests listed in the following sections. The type of imaging system, whether film-based, CR, or DR, to which the quality control tests apply, is identified. Alternative tests can be performed in place of those specified if it can be shown that the test is capable of verifying the necessary parameter or performance.

The quality control tests and frequencies indicated in this safety code are for general application to all dental X-ray equipment. However, any additional quality control tests or requirements for more frequent testing as indicated by the manufacturer for a specific dental X-ray device should be followed.

#### C.3.1. Daily Quality Control Testing

Daily quality control tests are listed in Table 3. The X-ray systems to which the tests are applicable, and the test numbers corresponding to the descriptions following the table are provided. These tests must be performed at the beginning of each day that dental radiography

is conducted before commencing patient examinations and processing any patient images. These tests should be able to be performed by dental X-ray equipment operators.

**Table 3. Daily Quality Control Tests**

Quality Control Procedures Under Evaluation	Intra-oral System		Panoramic System		Cephalometric System		CBCT System
	Film-based	CR or DR	Film-based	CR or DR	Film-based	CR or DR	
Equipment Warm-up	D1	D1	D1	D1	D1	D1	D1
Meters Operation	D2	D2	D2	D2	D2	D2	D2
Equipment Conditions	D3	D3	D3	D3	D3	D3	D3
Darkroom Cleanliness	D4		D4		D4		
Film Processing	D5		D5		D5		

\* CR: Computed Radiography, DR: Digital Radiography, CBCT: Cone Beam Computed Tomography

- D1. *Equipment Warm-up* – The manufacturer's recommended warm up procedure must be followed. The warm up procedure must be repeated if the equipment is left idle for an extended period of time. It is important to note that all components of the imaging system which are routinely used must be warmed up, including computer display devices and printers.
- D2. *Meters Operation* – Meters and visual and audible indicators should be checked for proper function.
- D3. *Equipment Conditions* – X-ray equipment conditions should be visually inspected for loose or broken components and cleanliness. The X-ray source assembly should be checked for motion or vibration during operation. Visual inspection should also be conducted of all other components of the imaging system.
- D4. *Darkroom Cleanliness* – In order to maintain the cleanliness of the darkroom, all working surfaces, tops of counters and the floor should be cleaned daily. Dust and debris can more easily be seen using a UV-B lamp.
- D5. *Film Processing* – Film processor function must be evaluated every morning before performing clinical examinations, after the processor has been turned on and has reached the required development temperature; and at other times as required, such as after a replenishment rate change.

The following quality control tests must also be performed:

- (i) The film processing solution levels must be checked to ensure agreement with the manufacturers' recommended baseline levels for the particular processor and film type, for the given number of films processed daily.
- (ii) The displayed processor temperature must be checked to ensure agreement with the manufacturers' recommended baseline level for the particular processor and film used. If film processing problems are detected during daily test film processing, it may be necessary to verify the pH of the developing chemicals, the developing time, specific gravity and replenishment rate.
- (iii) Test film processing with an appropriate dental quality control (QC) step wedge tool must be performed in order to monitor the performance of the image processing system. A step wedge tool can effectively detect X-ray imaging deficiencies before significant degradation of radiographic quality occurs. Step wedge test films must be within  $\pm 1$  step of the baseline film.

Test equipment for the daily quality control testing is listed in Table 4.

**Table 4. Daily Quality Control Test Equipment**

Item	Equipment	Systems*	Reference
1	Phantom (if needed for manufacturer's recommended warmup procedure)	FB, CR, DR, IO, PN, CP, CBCT	D1
2	Ultraviolet Light	FB, IO, PN, CP	D4
3	Dental QC test tool for film (e.g. Stepwedge)	FB, IO, PN, CP	D5

\* FB: Film Based, CR: Computed Radiography, DR: Digital Radiography, IO: Intra-oral, PN: Panoramic, CP: Cephalometric, CBCT: Cone Beam Computed Tomography

### C.3.2. Monthly Quality Control Testing

Monthly quality control tests are listed in Table 5. The X-ray systems to which the tests are applicable, and the test numbers corresponding to the descriptions following the table are provided. These tests should be able to be performed by dental staff.

**Table 5: Monthly Quality Control Tests**

Quality Control Procedures Under Evaluation	Intra-oral System		Panoramic System		Cephalometric System		CBCT System
	Film-based	CR or DR	Film-based	CR or DR	Film-based	CR or DR	
Cassette, Screen, Imaging Plate and Image Receptor Cleanliness and Condition	M1	M1	M1	M1	M1	M1	
Visual Inspection of Cleanliness of Imaging Systems	M2	M2	M2	M2	M2	M2	M2
Darkroom Light Conditions	M3		M3		M3		
Darkroom temperature and Humidity Conditions	M4		M4		M4		
Film Processor Operation	M5		M5		M5		
Viewboxes Condition	M6		M6		M6		
Electronic Display Device Performance		M7		M7		M7	M7
Digital Image Quality Evaluation		M8		M8		M8	M8
Reject/Retake Analysis		M9		M9		M9	M9

\* CR: Computed Radiography, DR: Digital Radiography, CBCT: Cone Beam Computed Tomography

**M1. Cassette, Screen, Imaging Plate and Image Receptor Cleanliness and Condition** – Cassettes, screens, imaging plates and intra-oral CR and DR image receptors must be kept clean of dust, dirt and other items which may come into contact with them. Manufacturer recommended cleaners and cleaning procedures should be used. An inspection of screens for dust particles should be done with an ultraviolet light. Cassettes, screens, imaging plates and intra-oral CR and DR image receptors must be inspected for damage, including wear, warping, dents and cracks. The cable on DR image receptors must also be checked for damage (e.g. fraying). Cassettes must be checked for fatigue of foam compression material and closure mechanism, and light leaks.

- M2. *Visual Inspection of Cleanliness of Imaging Equipment* – X-ray imaging equipment and associated apparatus must be inspected for dust and dirt on or near the image reception area where they may negatively affect image quality. For CR systems, the imaging plate loading and unloading mechanism in the reader must be cleaned and lubricated if necessary, according to manufacturer instructions. Display monitors should be kept clean and basic functionality confirmed (power on/off, visible display).
- M3. *Darkroom Light Conditions* – A visual test must be performed in the darkroom and for the day light system to ensure that they are light tight and that other sources of light such as illuminated light switches and computer power supplies do not cause film fogging. Particular attention must be paid to the door seal and the mounting of the film processor if the film insertion to the processor is done through a wall. The assessment of darkroom light conditions should be made after a 10 to 15 minute period of adaptation to the dark conditions with safelights turned off.
- M4. *Darkroom temperature and Humidity Conditions* – A verification of the darkroom temperature and humidity should be conducted. The temperature should be between 15°C and 23°C and the humidity between 40% and 60%.
- M5. *Film Processor Operation* – The following quality control tests must be performed on a film processing system.
- (i) The accuracy of the processor temperature display must be checked against a non-mercury thermometer. The processor developer temperature should be accurate to within 0.5°C.
  - (ii) The replenishment rate must be compared with the manufacturers' recommended baseline level for the particular processor and film type, for the given number of films processed daily and for the method of processing.
  - (iii) All processing solutions should be checked against manufacturer specifications. If required, processing solutions should be changed and solution tanks cleaned.
- M6. *Viewboxes Condition* – Viewboxes must be inspected visually for cleanliness, viewing area discolouration and improper illumination.
- M7. *Electronic Display Device Performance* – The performance of all electronic display devices used to view images from digital systems, as well as those obtained through scanning of radiographic films, must be checked using a test pattern such as the SMPTE or a TG18 test pattern, which are freely available online. For closed systems, where a suitable test pattern is not available on the system, a test pattern generator equipped with the appropriate test patterns must be utilized. Where a system does not have the capability to display an externally provided pattern, the manufacturer recommended quality control procedures must be followed. The following four rapid tests must be performed: (1) resolution: verify that the line bar patterns at center and corners of image are distinguishable; (2) grey steps



and alphanumerics: verify that each grey step (0% to 100%) is distinguishable and that alphanumeric characters are sharp and in focus; (3) contrast/brightness: verify that the 5% and 95% boxes inset in 0% and 100% areas are visible; (4) geometric distortions: verify the general appearance of the test pattern to ensure that all lines appear straight and continuous, the pattern is square and that there are no blurred or flickering regions. The quality control procedures and acceptance criteria recommended by the American Association of Physicists in Medicine (AAPM)<sup>34</sup> can also be used.

**M8. Digital Image Quality Evaluation** – For CR and DR systems, an evaluation must be made of the digital image quality. Upon acquiring an image with an appropriate digital phantom, the following criteria must be evaluated:

- (i) image artifacts – no artifacts which could interfere with clinical interpretation, such as light or dark spots, scratches or bands that indicate damage on the image receptor; and
- (ii) uniformity – images must appear uniform.

**M9. Reject/Retake Analysis** – For both film/screen and digital dental X-ray systems, an analysis must be done of the repeat records to identify and correct any trends or errors. Repeat images are defined as images taken due to inadequate quality. This does not include images taken for quality control purposes or images taken to acquire additional views. Repeat records must be maintained and analyzed individually for each dental X-ray system. Facilities must maintain records for every repeat, the reason for the repeat along with any corrective actions, immediately after the repeat image is taken. If images contain some patient diagnostic information, they should be maintained in the patient file. The repeat rate should be 5% or within an acceptable range that reflects the individual facility's clinical practice and equipment, as determined by an expert in radiation protection. Repeat rates above this threshold should be investigated and possible corrective action taken to ensure that image quality and patient doses are optimized. Repeat rates below this threshold should be investigated and possible corrective action taken unless clinical data indicate this threshold should be lower. Low repeated image rates can signal acceptance of poor quality images, or patient doses that are too high resulting in highest quality images in all cases (instead of using minimum dose required to meet diagnostic objectives).

Test equipment for the monthly quality control testing is listed in Table 6.

**Table 6. Monthly Quality Control Test Equipment**

Item	Equipment	Systems*	Reference
1	Ultraviolet Light	FB, IO, PN, CP	M1

Item	Equipment	Systems*	Reference
2	Screen Cleaner (as recommended by manufacturer)	FB, IO, PN, CP	M1
3	Hygrometer	FB, IO, PN, CP	M4
4	Thermometer (non-mercury) Accuracy: $\pm 0.3$ °C Reproducibility: $\pm 0.1$ °C	FB, IO, PN, CP	M4, M5
5	Hypo Test Kit	FB, IO, PN, CP	M5
6	Test pattern(s) for evaluation of electronic display device performance (ex. SMPTE, TG18-QC, TG18-PQC)	FB, CR, DR, IO, PN, CP, CBCT	M7
7	Digital Image Quality Phantom (specific for type of equipment)	CR, DR, IO, PN, CP, CBCT	M8

\* FB: Film Based, CR: Computed Radiography, DR: Digital Radiography, IO: Intra-oral, PN: Panoramic, CP: Cephalometric, CBCT: Cone Beam Computed Tomography

### C.3.3. Annual Quality Control Testing

Annual quality control tests are listed in Table 7. The X-ray systems to which the tests are applicable, and the test numbers corresponding to the descriptions that follow the table are provided. These tests should be performed by the manufacturer or a service provider with appropriate expertise.

**Table 7. Annual Quality Control Tests**

Quality Control Procedures Under Evaluation	Intra-oral System		Panoramic System		Cephalometric System		CBCT System
	Film- based	CR or DR	Film- based	CR or DR	Film- based	CR or DR	
Safelight Test	A1		A1		A1		
Accuracy of Loading Factors	A2	A2	A2	A2	A2	A2	A2

Quality Control Procedures Under Evaluation	Intra-oral System		Panoramic System		Cephalometric System		CBCT System
	Film-based	CR or DR	Film-based	CR or DR	Film-based	CR or DR	
Radiation Output Reproducibility	A3	A3	A3	A3	A3	A3	A3
Radiation Output Linearity	A4	A4	A4	A4	A4	A4	A4
X-ray Beam Filtration	A5	A5	A5	A5	A5	A5	A5
Automatic Exposure Control	A6	A6	A6	A6	A6	A6	A6
X-ray Beam Collimation	A7	A7	A7	A7	A7	A7	A7
Image Noise and Uniformity		A8		A8		A8	A8
Image Artifacts	A9	A9	A9	A9	A9	A9	A9
Spatial Resolution	A10	A10	A10	A10	A10	A10	A10
Contrast Detectability	A11	A11	A11	A11	A11	A11	A11
Geometric Accuracy							A12
Dosimetric Indicators Accuracy	A13	A13	A13	A13	A13	A13	A13
Viewboxes Condition	A14		A14		A14		
Digital Image Quality Evaluation							A15
Electronic Display Device Performance		A16		A16		A16	A16
Integrity of Protective Equipment	A17	A17	A17	A17	A17	A17	A17
General Preventative Maintenance	A18	A18	A18	A18	A18	A18	A18

\* CR: Computed Radiography, DR: Digital Radiography, CBCT: Cone Beam Computed Tomography

- A1. *Safelight test* – An evaluation must be made of the effects of the safelight on film optical density. To test for light leakage in the darkroom or in a daylight loader, a coin should be placed on a new film on the darkroom counter or in the daylight loader for a duration of two minutes. After developing the film, if an image of the coin is visible it indicates light leaks. For daylight loaders, if the problem is resolved by using the processor in the dark, this is an indication that the light leak is due to the daylight loader.
- A2. *Accuracy of Loading Factors* – For any combination of loading factors, the X-ray tube voltage must not deviate from the selected value by more than 10%, the X-ray tube current must not deviate from the selected value by more than 20%, the loading time for intra-oral dental X-ray equipment must not deviate from the selected value by more than the larger of 5% or 20 ms (if the equipment uses a one-peak high voltage generator, this does not apply for loading times shorter than 0.1 s), the loading time for extra-oral dental X-ray equipment must not deviate from the selected value by more than (5% + 50 ms), and the current-time product for extra-oral dental X-ray equipment must not deviate from the selected value by more than (10% + 0.2 mAs).
- A3. *Radiation Output Reproducibility* – The X-ray tube radiation output shall be high enough to minimize irradiation time to eliminate perceptible motion artifacts. For any combination of operating loading parameters, the coefficient of variation of any five consecutive irradiation measurements, taken at the same source to image receptor distance within a time period of one hour, is no greater than 0.05.
- A4. *Radiation Output Linearity* – For any pre-selected value of X-ray tube voltage, the quotient of the average air kerma measurement divided by the indicated current time product obtained at two settings of X-ray tube current or X-ray tube current-time product must not differ by more than 0.10 times their sum, that is,
- $$|X_1 - X_2| \leq 0.1 (X_1 + X_2)$$
- where  $X_1$  and  $X_2$  are average air kermas (exposures) per current time product. The values of  $X_1$  and  $X_2$  must be determined at (a) where the X-ray tube current is fixed, at each combination of two settings of the controlling timer, and (b) where the irradiation time is fixed, at each combination of two X-ray tube current settings (if the equipment uses a one-peak high voltage generator, the range of X-ray tube current time product must be limited to irradiation times not shorter than 80 ms).
- A5. *X-ray Beam Filtration* – The first half-value layer of aluminum must be measured. For a selected X-ray tube voltage, the measured values must not be less than the values shown in the table presented in the Schedule II, Part II, Section 17 of the *Radiation Emitting Devices Regulations*<sup>38</sup> in force at the time of sale, or resale, of the X-ray equipment.
- A6. *Automatic Exposure Control* – For film-based or digital systems, the automatic exposure control must be evaluated to ensure it meets the requirements of A3.

The performance of the backup timer must be verified to ensure safe performance of the equipment. For extra-oral dental X-ray equipment, the current time product must not exceed 640 mAs or the product of X-ray tube voltage, X-ray tube current and irradiation time must not exceed 64 kJ. For intra-oral dental X-ray equipment, the current time product must not exceed 32 mAs or the product of X-ray tube voltage, X-ray tube current and irradiation time must not exceed 3.2 kJ.

- A7. *X-ray Beam Collimation* – An evaluation of the beam limiting device must be made to ensure that the equipment is capable of aligning the X-ray field with the image receptor as per the requirements in Schedule II, Part II, Section 21 of the *Radiation Emitting Devices Regulations*<sup>38</sup> in force at the time of sale, or resale, of the X-ray equipment. For the verification of a digital system, the use of radiochromic film as a replacement for cassettes with radiological films can allow this test to be carried out.
- A8. *Image Noise and Uniformity* – An assessment must be made of the image noise and uniformity. The Signal-to-Noise Ratio (SNR) should be calculated, when possible, by measuring the mean pixel value and standard deviation in a region of interest within the image. The test should be done using a phantom specific for dental X-ray equipment, with mean pixel values and standard deviation of signal values determined in phantom regions as specified in the instructions for the phantom. The measured noise value must be within established limits. The uniformity of the signal across the different regions of interest at the periphery and the center of the phantom must be within established limits.
- A9. *Image Artifacts* – Images must be assessed to ensure that unacceptable artifacts are not present.
- A10. *Spatial Resolution* – An evaluation must be made of the spatial resolution of the equipment. Spatial resolution is the ability to resolve objects in a resultant image when the difference in the attenuation between the objects and the background is large compared to noise. The manufacturer's recommended test procedures must be followed if available. For intra-oral image receptors, spatial resolution can be evaluated with a line pair test tool. For cone beam computed tomography devices, spatial resolution can be evaluated by the modulation transfer function (MTF). For each mode of operation, the spatial resolution must be within established limits.
- A11. *Contrast Detectability* – An evaluation should be made of contrast detectability. The contrast detectability is the ability to resolve different objects from the background when the difference in attenuation between the objects and the background is small compared to noise. The manufacturer's recommended test procedures should be followed if available. For intra-oral image receptors, contrast detectability can be evaluated with a low-contrast test tool. For each mode of operation, the contrast resolution should be within established limits.

- A12. *Geometric Accuracy* – An evaluation must be made of the geometric accuracy of the image receptor with a specific phantom. Geometric accuracy is the ability of the device to accurately indicate distances and angles. Distance measurements should be made along the perpendicular axis. The geometric accuracy should be within  $\pm 0.5$  mm for distances and  $\pm 2^\circ$  for angles.
- A13. *Dosimetric Indicators* – Dose measurements for frequently performed examinations must be within established limits. For intra-oral dental X-ray equipment, incident air kerma (measured at the end of the cone) should be measured. For panoramic and CBCT dental X-ray equipment, the air kerma area product should be measured. For cephalometric dental X-ray equipment, either the incident air kerma or air kerma area product should be measured. Measurements should be performed using the equipment geometry and loading conditions representative of those used clinically. Dose values obtained should be used for the annual review of the facilities DRLs. Accuracy of displayed dosimetric indicators on the device must also be evaluated and be within manufacturer specifications.
- A14. *Viewboxes Condition* – Viewboxes must be inspected visually for cleanliness, viewing area discolouration and improper illumination. The view box luminance should be at least 2,500 nits (cd/m<sup>2</sup>). The light output from the viewboxes should be uniform to within 10%.
- A15. *Digital Image Quality Evaluation* – For CBCT equipment, an evaluation of the accuracy of the voxel values must be made. Using a CBCT digital image quality phantom, the mean voxel value and the standard deviation, within a region of interest for each density of material in the phantom, must remain within the established baseline and acceptable limits of variation. The mean voxel values should not deviate from the established baseline values by more than  $\pm 10\%$ .
- A16. *Electronic Display Device Performance* – The performance of all electronic display devices used for the interpretation of clinical images must not compromise image quality and ultimately patient care. The performance assessment of display devices must be verified using a test pattern such as the SMPTE or TG18 test patterns. For closed systems, where a suitable test pattern is not available on the system, a test pattern generator equipped with the appropriate test patterns must be utilized. Where a system does not have the capability to display an externally provided pattern, the manufacturer recommended quality control procedures must be followed. The annual quality control tests recommended by the American Association of Physicists in Medicine<sup>40</sup>, including test procedures and acceptance criteria should be used. The display system must be warmed up prior to testing and attention must be given to ensure the ambient light levels are appropriate and representative of conditions under which clinical images are viewed. A viewing distance of 30 cm is recommended.
- A17. *Integrity of Protective Equipment* – All protective equipment must be examined to ensure they are not defective. Visual, tactile or X-ray examinations may be used to detect tears,

perforations and thinning of the protective lead lining. Lead aprons with a lead equivalence of 0.5 mmPb where the length of the defect is greater than 5.4 cm are not acceptable. Protective equipment with a lead equivalence of 0.5 mmPb having a defect in the vicinity of the thyroid which is longer than 1.8 cm or the reproductive organs which is longer than 1.7 cm must not be used<sup>48</sup>. Personal judgment should be used when small defects are located along the edges of the protective equipment and when defects are due to stitching of the equipment. All protective equipment, when not in use, should be stored in accordance to the manufacturers' recommendations.

A18. *General Preventative Maintenance* – Preventive maintenance of the X-ray equipment and accessories is necessary to prolong the life of the equipment. An annual inspection must be conducted for structural integrity, cleanliness, ease of movement of all components and any other procedures recommended by the manufacturers.

Test equipment for the annual quality control testing is listed in Table 8.

**Table 8. Annual Quality Control Test Equipment**

Item	Equipment	Systems*	Reference
1	Stopwatch	FB, IO, PN, CP	A1
2	Non-invasive voltage meter Accuracy: $\pm 1.5$ kV Reproducibility: $\pm 0.5$ kV	FB, CR, DR, IO, PN, CP, CBCT	A2
3	Irradiation time meter Accuracy: $\pm 5\%$ Reproducibility: $\pm 1\%$	FB, CR, DR, IO, PN, CP, CBCT	A2
4	Current meter Accuracy: $\pm 1\%$ Reproducibility: $< 0.5\%$	FB, CR, DR, IO, PN, CP, CBCT	A2
5	Dosimeter Accuracy: $\pm 5\%$ Reproducibility: $\pm 1\%$	FB, CR, DR, IO, PN, CP, CBCT	A3, A4, A5, A13
6	Aluminum filter ( $> 99.9\%$ purity) Accuracy: 1% thickness	FB, CR, DR, IO, PN, CP, CBCT	A5

Item	Equipment	Systems*	Reference
7	Multiple sheets of uniform, tissue equivalent attenuator (covering range of clinical patient thicknesses)	FB, CR, DR, IO, PN, CP, CBCT	A6, A8, A9, A10
8	X-ray Beam Alignment Tool	FB, CR, DR, IO, PN, CP, CBCT	A7
9	Radiochromic Film	FB, CR, DR, IO, PN, CP, CBCT	A7, A13
10	Ruler(s) or measuring tape	FB, CR, DR, IO, PN, CP, CBCT	A7, A16, A17
11	ROI capability or QC software for image analysis	CR, DR, IO, PN, CP, CBCT	A8
12	Spatial Resolution test tool (specific for type of equipment)	FB, CR, DR, IO, PN, CP, CBCT	A10
13	Contrast Detectability test tool (specific for type of equipment)	FB, CR, DR, IO, PN, CP, CBCT	A11
14	Geometric Accuracy test tool	CBCT	A12
15	Light meter (for measurement of luminance and Illuminance)  Accuracy: $\pm 10\%$  Reproducibility: $\pm 5\%$	FB, IO, PN, CP	A14,
16	Digital Image Quality Phantom	CBCT	A15
17	Test Pattern(s) for evaluation of electronic display device performance (ex. TG18 or SMPTE)	CR, DR, IO, PN, CP, CBCT	A16

\* FB: Film Based, CR: Computed Radiography, DR: Digital Radiography, IO: Intra-oral, PN: Panoramic,

CP: Cephalometric, CBCT: Cone Beam Computed Tomography



## Appendix I: Federal/Provincial/Territorial Regulatory Authorities

A listing of Federal/Provincial/Territorial Radiation Protection Committee members is available at the following link:

<https://www.canada.ca/en/health-canada/services/environmental-workplace-health/radiation/federal-provincial-territorial-radiation-protection-committee.html>

### Federal Government

Consumer and Clinical Radiation Protection Bureau, Health Canada  
(Responsible for the interpretation of Safety Codes, and administration of *Radiation Emitting Devices Act* and its Regulations)

E-mail: [HC.ccrpb-pcrpcc.SC@canada.ca](mailto:HC.ccrpb-pcrpcc.SC@canada.ca)

Website: <https://www.canada.ca/en/health-canada/corporate/contact-us/consumer-clinical-radiation-protection-bureau.html>

Medical Devices Directorate, Health Canada  
(Responsible for the licensing of medical devices and administration of the *Food and Drugs Act* and Medical Devices Regulations)

E-mail: [mdb\\_enquiries@hc-sc.gc.ca](mailto:mdb_enquiries@hc-sc.gc.ca)

Website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices.html>

Labour Program, Employment and Social Development Canada  
(Federal Authority responsible for administration of the *Canada Labour Code* and Canada Occupational Health and Safety Regulations)

Contact: <https://www.canada.ca/en/employment-social-development/services/labour-contact.html>

Website: <https://www.canada.ca/en/services/jobs/workplace/health-safety.html>

### British Columbia

Senior Manager, Risk Analysis Unit

WorkSafeBC

E-mail: [Colin.Murray@worksafebc.com](mailto:Colin.Murray@worksafebc.com) or [riskanalysisunit@worksafebc.com](mailto:riskanalysisunit@worksafebc.com)

Website: <http://worksafebc.com/en>

## **Alberta**

Specialized Professional Services

Occupational Health & Safety Program Delivery

Alberta Labour and Immigration

E-mail: [LBR.RadiationProgram@gov.ab.ca](mailto:LBR.RadiationProgram@gov.ab.ca)

Website: <https://www.alberta.ca/register-radiation-equipment.aspx>

## **Saskatchewan**

Radiation Safety Unit

Ministry of Labour Relations and Workplace Safety

E-mail: [radiationsafety@gov.sk.ca](mailto:radiationsafety@gov.sk.ca)

Website: <https://www.saskatchewan.ca/business/safety-in-the-workplace/hazards-and-prevention/radiation>

## **Manitoba**

Radiation Protection Services

Medical Physics Division

CancerCare Manitoba

E-mail: [ifife@cancercare.mb.ca](mailto:ifife@cancercare.mb.ca)

Website: <https://www.cancercare.mb.ca/Research/medical-physics/radiation-protection-services>

## **Ontario (for issues related to patient and public safety)**

X-ray Inspection Service

Ontario Ministry of Health

E-mail: General Enquiries: [xris@ontario.ca](mailto:xris@ontario.ca); Shielding applications: [xrisplans@ontario.ca](mailto:xrisplans@ontario.ca)

Website: <http://www.health.gov.on.ca/en/>

## **Ontario (for issues related to worker safety)**

Manager, Radiation Protection Service

Occupational Health and Safety Branch

Ministry of Labour, Training and Skills Development

E-mail: [RadiationProtection@ontario.ca](mailto:RadiationProtection@ontario.ca)

Website: <http://www.labour.gov.on.ca/>

## **Quebec**

Direction du Génie biomédical, de la logistique et de l'approvisionnement (DGBLA)

Ministère de la Santé et des Services sociaux (MSSS)

E-mail: [dgai@msss.gouv.qc.ca](mailto:dgai@msss.gouv.qc.ca)

Website: <https://www.msss.gouv.qc.ca/index.php>

## **New Brunswick**

WorkSafeNB

Prevention Division

Manager - Ergonomics & Occupational Hygiene

E-mail: [prevention@ws-ts.nb.ca](mailto:prevention@ws-ts.nb.ca)

Website: <https://www.worksafenb.ca/>

## **Nova Scotia**

General Inquiries and Reporting

Occupational Health and Safety Division

Nova Scotia Department of Labour, Skills and Immigration

Toll Free 1-800-952-2687 (24 Hrs)

E-mail: [ohsdivision@novascotia.ca](mailto:ohsdivision@novascotia.ca)

Website: <https://novascotia.ca/lae/healthandsafety/>

## **Prince Edward Island**

Workers Compensation Board of PEI

Occupational Health and Safety Division

E-mail: [ohs@wcb.pe.ca](mailto:ohs@wcb.pe.ca)

Website: <http://www.wcb.pe.ca>

## **Newfoundland and Labrador**

Department of Digital Government and Service NL

Occupational Health and Safety Division

E-mail: [nwilson@gov.nl.ca](mailto:nwilson@gov.nl.ca)

Website: <https://www.gov.nl.ca/dgsnl/ohs/>

## **Northwest Territories and Nunavut**

Occupational Health and Safety

Government of the Northwest Territories

E-mail: [gnwt\\_ohs@gov.nt.ca](mailto:gnwt_ohs@gov.nt.ca)

Website: <https://my.hr.gov.nt.ca/health-safety>

## **Yukon Territory**

Occupational Health and Safety

Yukon Workers' Compensation Health and Safety Board

E-mail: [Work.Safe@wcb.yk.ca](mailto:Work.Safe@wcb.yk.ca)

Website: <https://wcb.yk.ca/>

## Appendix II: Dose Limits for Occupational Ionizing Radiation Exposures

For the purpose of this Safety Code, individuals may be classified in one of two categories: (1) radiation workers, and (2) members of the public and persons who are not declared radiation workers. The dose limits are given for both categories in Table AII.1. These dose limits are based on the latest recommendations of the International Commission on Radiological Protection (ICRP) as specified in ICRP Publication 103<sup>49</sup> and 118<sup>50</sup>.

Dose limits for occupationally-exposed dental workers apply only to irradiation resulting directly from their occupation and do not include radiation exposure from other sources, such as medical diagnosis and background radiation.

**Table AII.1. Annual Dose Limits Applicable Body Organ or Tissue for Dental Workers and Members of the Public**

Applicable Body Organ or Tissue	Radiation Workers	Members of the Public and Persons who are Not Declared Radiation Workers
Whole Body	20 mSv effective dose per year averaged over a defined 5 year period and 50 mSv in any single year.	1 mSv effective dose
Lens of the eye	20 mSv equivalent dose per year averaged over a defined 5 year period and 50 mSv in any single year.	15 mSv equivalent dose
Skin	500 mSv equivalent dose	50 mSv equivalent dose
Hands and Feet	500 mSv equivalent dose	-

1. It is emphasized that any irradiation involves some degree of risk and the levels suggested in this Appendix are maximum values. All doses must be kept as low as reasonably achievable and any unnecessary radiation exposure must be avoided.
2. The ICRP does not recommend discrimination in the dose limits between men and women of reproductive capacity, if the dose is received at an approximately regular rate.
3. For radiation workers, once pregnancy has been declared, the fetus must be protected from X-ray exposure for the remainder of the pregnancy. An effective dose limit of 4 mSv must be applied, for the remainder of the pregnancy, from all sources of radiation.

Under the scope of this document, occupational exposures to pregnant workers arise mainly from scattered X-radiation. In this case, the most effective method of monitoring exposures to the fetus is to measure the equivalent dose to the surface of the abdomen using a personal radiation dosimeter.

4. For technologists-in-training and students, the recommended dose limits for members of the public should apply.
5. ICRP does not recommend different limits for individual organs. For radiation workers, ICRP believes that deterministic effects will be prevented by applying an equivalent dose limit of 500 mSv in a year to all tissues except the lens of the eye, for which it recommends a limit of 20 mSv in a year.
6. For the skin, the equivalent dose is averaged over its whole area. In situations where deterministic effects are possible, the recommended equivalent dose limit for the skin is 500 mSv and is averaged over areas of no more than 1 cm<sup>2</sup>. This limit applies to the skin of the face and hands.
7. Some provincial or territorial jurisdictions may have different dose limits for some dental workers who are occupationally exposed to X-rays. The appropriate regulatory authority, listed in Appendix I, should be consulted to determine the dose limits in effect in a particular jurisdiction.

## Appendix III: Facility Radiation Protection Checklist

Table AIII.1: Facility Radiation Protection Checklist

Description	Yes / No	Reference Subsection
<b>Personnel Qualifications and Responsibilities</b>		
Do all personnel possess the required qualifications and training to carry out all of their responsibilities?		A.1.0
Owner:		A.1.1
Coordinator of the Radiation Protection Program:		A.1.2
X-ray Equipment Operator:		A.1.3
Prescribing Dental Practitioner:		A.1.4
Expert in Radiation Protection		A.1.5
Repair and Maintenance Personnel		A.1.6
<b>Procedures for Minimizing Radiation Exposure to Personnel</b>		
In general, are all required and recommended procedures for minimizing exposures to personnel in place and being followed?		A.2.0
In general, are all required and recommended procedures for operation of radiographic equipment in place and being followed?		A.2.1
If hand-held equipment is used, are all required and recommended procedures for minimizing exposures to personnel from hand-held equipment in place and being followed?		A.2.2
<b>Procedures for Minimizing Radiation Exposure to Patients</b>		
In general, are the guidelines for the prescription of dental X-ray examinations being followed?		A.3.1
Are dental X-rays justified by a clinical evaluation of the patient, as opposed to routine or screening examinations?		A.3.1
Are previous radiographs or reports consulted prior to prescribing additional dental X-ray examinations?		A.3.1
In general, are the guidelines for dental X-ray examinations of pregnant employee being followed?		A.3.1

In general, are all required and recommended procedures for carrying out dental X-ray examinations in place and being followed?		A.3.2
Do equipment operators select techniques and loading factors such that their combination produces the minimum patient exposure consistent with acceptable image quality and the clinical purpose of the examination?		A.3.2
Is adequate patient shielding available and used where appropriate and practicable?		A.3.2
Have presettings and loading factors for all dental X-ray devices been optimized to ensure patient radiation doses are minimized?		A.3.3
<b>Facility Requirements</b>		
Do the dose rates outside the controlled areas meet the regulatory dose limits for the public?		B.1.1
Is there an up-to-date floor plan available containing the information required in subsection B1.2.1?		B.1.2
Is the operator able to observe the patient during a panoramic or CBCT exposure?		B.1.2
Is access restricted in controlled areas during an irradiation?		B.1.2
Are the parameters governing structural shielding requirements known and documented for all of the X-ray equipment in the facility?		B.1.2
Were the facility layout and construction approved by appropriate regulatory authorities?		B.1.3
Have any modifications been made to the facility?		B.1.3
If modifications have been made to the facility, was a safety assessment performed by an expert in radiation protection prior to the modifications being made?		B.1.3
Were shielding calculations performed by an individual with current expertise in structural shielding design and accepting methods of performing these calculations?		B.1.3

Does the facility meet all applicable federal, provincial or territorial regulatory requirements?					B.1.3
<b>Equipment Requirements</b>					
Does the equipment meet all applicable regulatory requirements?					B.2.1
At time of purchase, was all new, used and refurbished medical equipment confirmed to be licensed and meet the:					B.2.1
<div style="text-align: center;">Radiation Emitting Devices Regulations?</div> <div style="text-align: center;">Medical Devices Regulations?</div>					
Was a needs analysis performed to identify the appropriate X-ray equipment required to meet the clinical imaging needs?					B.2.2
Was acceptance testing performed on all equipment at time of purchase prior to clinical use?					B.2.3
Were results from acceptance testing used to set baseline values and limits on operational performance of the X-ray equipment?					B.2.3
Does all equipment meet the necessary performance requirements?					B.2.3
Is existing equipment periodically assessed for the possibility of upgrading to improve safety and performance?					B.2.4
If retrofitting a digital image receptor into a new or existing dental X-ray system, was the system optimized for all manual techniques and anatomical presetsings?					B.2.5
<b>Equipment Information</b>					
<b>Type of X-ray Equipment</b>	<b>Manufacturer</b>	<b>Model Designation</b>	<b>Serial Number</b>	<b>Date of Manufacture</b>	<b>Weekly Workload</b>



Imaging Processing Systems		
Are the recommendations for film processing systems followed at the facility?		
X-ray film storage		B.3.1
Cassette and Screen Maintenance		B.3.1
Darkroom Conditions		B.3.1
Film Processing		B.3.1
Viewboxes Conditions		B.3.1
Is the management of silver containing waste carried out in accordance to provincial and municipal requirements?		B.3.1
Does the facility perform digital image processing? If yes, what types of digital image acquisition systems are used? CR Systems: DR Systems:		B.3.2
For the digital imaging systems, is the manufacturer-specific quality control program being followed?		B.3.2
Radiation Protection Surveys		
Does the facility undergo Radiation Protection Surveys at regular intervals?		B.5.1
Are copies of past Radiation Protection Survey reports retained and available if needed?		B.5.1
Do survey reports include all of the necessary information?		B.5.2
Quality Assurance Program		
Is there a documented quality assurance program at this facility?		C.1.0
Is the establishment of quality control and administrative procedures documented?		C.1.2
Is equipment used for quality control testing calibrated?		C.3.0
Is equipment used for daily quality control testing available on-site at the facility?		C.3.1

Are individuals trained in the proper operation of quality control test equipment?		C.3.0-C.3.3
Does the facility Quality Assurance program include the required tests of this Safety Code or their equivalent?		
For film-based radiographic equipment		C.3.1-C.3.3
For digital radiographic equipment		C.3.1-C.3.3
Does the facility Quality Assurance program follow the recommended frequency of testing of this Safety Code?		
For daily quality control testing		C.3.1
For monthly quality control testing		C.3.2
For annual quality control testing		C.3.3

## Appendix IV: Radiation Measurement Units

### Exposure

Following the lead of the International Electrotechnical Commission, the **air kerma** (in **gray, Gy**) replaces the **exposure** (in **roentgen, R**) as the measure of exposure. The relationship between the two units is as follows:

$$\begin{array}{llll} 1 \text{ Gy} & \sim & 115 \text{ R} & 1 \text{ R} \sim 8.73 \text{ mGy} \\ 1 \text{ mGy} & \sim & 115 \text{ mR} & 1 \text{ mR} \sim 8.73 \text{ }\mu\text{Gy} \end{array}$$

### Absorbed Dose

The **gray (Gy)** replaces the **rad (rad)** as the unit of absorbed dose. The relationship between the two units is as follows:

$$\begin{array}{llll} 1 \text{ Gy} & \sim & 100 \text{ rad} & 1 \text{ rad} \sim 10 \text{ mGy} \\ 1 \text{ mGy} & \sim & 100 \text{ mrad} & 1 \text{ mrad} \sim 10 \text{ }\mu\text{Gy} \end{array}$$

### Equivalent Dose or Effective Dose

The **sievert (Sv)** replaces the **rem (rem)** as the unit of equivalent dose or effective dose. The relationship between the two units is as follows:

$$\begin{array}{llll} 1 \text{ Sv} & \sim & 100 \text{ rem} & 1 \text{ rem} \sim 10 \text{ mSv} \\ 1 \text{ mSv} & \sim & 100 \text{ mrem} & 1 \text{ mrem} \sim 10 \text{ }\mu\text{Sv} \end{array}$$

**Note:** m = milli =  $10^{-3}$ ;  $\mu$  = micro =  $10^{-6}$

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