



BC MANDATORY X-RAY INSPECTION PROGRAM
**SAFETY CODE 30 - RADIATION PROTECTION IN
DENTISTRY RECOMMENDED SAFETY PROCEDURES
FOR THE USE OF DENTAL X-RAY EQUIPMENT**
PRACTICE MANAGEMENT RESOURCE DIRECTORY

This document is a summary of issues found in Health Canada Safety Code 30 regarding worker and patient safety procedures and issues. These items are identified by the term **MUST**. The word "**MUST**" indicates a recommendation that is essential to meet the currently accepted standards of protection, while "should" indicates an advisory recommendation that is highly desirable and that is to be implemented where applicable.

With respect to the Workers' Compensation Board (WCB) regulations, items or issues associated with workers' safety, the term **MUST** is expected to be in compliance. Any questions concerning WCB issues should be directed towards the WCB.

The responsibilities have been classified and grouped into seven major categories:

Designated Responsibility	Health Canada Safety Code Section	Document Page
Owner	1.0, 3.1, 4.1, 4.2, 4.3, 5.2, 6.1-6.3, 7.1, 7.3-7.5, 8.0, 8.1, Appendix I, Appendix II	2-10
Owner/Operator	9.2	10-11
Operator	3.2	11-12
Manufacturer / Vendor / Distributor	5.1	12

For this and other issues, you should refer to your copy of the current Health Canada Safety Code for your profession. (Safety Code 30, downloadable for free from the website listed below)

Note: The section numbers follow each bullet.

Several complete Safety Codes could be found on the Health Canada web site:
<http://www.hc-sc.gc.ca/ehp/ehd/catalogue/rpb.htm>

- **1.0 - OWNER:** the use of dental radiological procedures **MUST** be carefully managed, because X-radiation has the potential for damaging healthy cells and tissues.
- **1.0 - OWNER:** For patients, the risk involved with exposure to radiation **MUST** always be weighed against the clinical benefit of an accurate diagnosis, and there **MUST** always be a conscious effort to reduce patient doses to the lowest practical levels and to eliminate unnecessary dental X-ray procedures.
- **3.1 - OWNER:** The **owner** is ultimately responsible for the radiation safety of a dental facility. The **owner** may delegate this responsibility to staff. In any event, one or more persons **MUST** undertake responsibility for:

1. Ensuring that the installation complies with all applicable regulatory requirements, including equipment registration with the appropriate regulatory agency;
 2. Establishing safe working conditions in accordance with the recommendations of this Safety Code and the statutory requirements of federal, provincial or territorial legislation, where applicable;
 3. Contacting the appropriate government agency when a new facility is being constructed, modification of an existing one is planned, or when dental X-ray equipment is purchased, to ensure that radiation barriers are adequate to meet the recommended effective dose limits given in Appendix I;
 4. Contacting the appropriate government agency to set periodic scheduled inspections for the facility. In some jurisdictions, the responsible agency has the mandate for setting inspection schedules;
 5. Ensuring that the equipment functions properly, is operated correctly, and is maintained by competent personnel only;
 6. Ensuring that operators are properly trained in the operation of the equipment being used;
 7. Ensuring that operators- in- training and inexperienced personnel operate dental X-ray equipment only under the direct supervision of an experienced operator;
 8. Implementing and maintaining a Quality Assurance program for the facility;
 9. Maintaining and keeping all records of the Quality Assurance program and records pertaining to the performance of dental X-ray equipment for the facility
 10. Promulgating rules of radiation safety and ensuring that staff are made aware of them; and
 11. Ensuring that operators understand the recommendations of this Safety Code.
- **4.1 - Owner: Design Criteria for Dental Facilities**
 In the planning of any dental facility, consideration **MUST** be given to the operating X-ray tube voltage, expected maximum workload of the equipment, orientation factors of the radiation barriers and occupancy factors for areas adjacent to the facility. Allowance should be made for possible future increases in these parameters. Certain basic principles **MUST** be observed when determining the shielding requirements for a room used routinely for dental radiography. These are:
 - (i) the radiation levels in controlled areas that are occupied routinely by radiation workers **MUST** be such that no radiation worker can receive more than 20 mSv per year; and
 - (ii) the radiation levels in uncontrolled areas **MUST** be such that no person can receive more than 1 mSv per year.

In general, radiation levels near dental X-ray equipment are such that the above limits can be exceeded. Reduction in radiation intensity can be accomplished by the use of a suitable combination of distance from the source of radiation and physical radiation shielding barriers. It **MUST** also be noted that the above recommended dose limits for radiation workers apply only to radiation exposure resulting directly from their occupation and do not include exposure from other sources, such as medical diagnosis and background radiation. The radiation shielding required to reduce radiation levels to within the acceptable limits may be determined on the basis of distance, maximum expected X-ray tube voltage (kilovolt), workload (milliampere- second per week), orientation factor, and occupancy factor, as described in *Appendix II*. To ensure that the radiation levels are always below acceptable limits the maximum expected workload and tube voltage should be used.

Complex shielding calculations should be performed only by individuals with in- depth knowledge of radiation protection requirements and radiation shielding barriers. When such calculations are required, contact the appropriate government agency for guidance. For installations under federal jurisdiction the responsible agency is the Radiation Protection Bureau, Health Canada, Ottawa, Ontario, K1A 1C1. Dental facilities that fall under provincial/ territorial jurisdiction **MUST** meet the requirements of the responsible agency in their respective jurisdiction. These requirements can be obtained by contacting the appropriate agency listed in Appendix IV.

- **4.2 - Owner: General Recommendations**

Protection of the **operator** and others near dental X-ray equipment should be achieved by:

1. Ensuring that the room containing the dental X-ray equipment is designed so that during the examination the operator is not exposed to the primary radiation beam and can keep a distance of at least 3 meters from the X-ray tube and from the patient. If it is not possible for an operator to keep at a distance of at least 3 meters 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 radiography;
3. Constructing shielding to form an unbroken barrier. Care should be taken in the use of shielding materials, especially lead, which **MUST** be adequately supported to prevent sagging;
7. Arranging for the final plans of the installation to be reviewed by the appropriate government agency when a new facility is constructed or modification to an existing one is made. The plans and accompanying documents **MUST** show:
 - dimensions and shape of the room where the dental X-ray equipment is operated;
 - materials used to construct the walls, floor and ceiling, and their thicknesses;
 - materials used in radiation shielding barriers, shielding dimensions, locations and thicknesses;
 - positions of all windows, doors, louvers, etc. , that may affect radiation protection requirements;
 - location and orientation of the dental X-ray equipment and dental chair, or other patient and film (cassette) supports;
 - location, use and accessibility of adjacent rooms, as well as the room above and below the facility;
 - expected maximum workload;
 - brief description of the X-ray unit(s) , containing at least the name of the manufacturer, model designation, operating X-ray tube voltages and X-ray tube current.

- **4.3 - OWNER: Radiation Protection Inspection**

Radiation protection inspections **MUST** be performed on a regular basis to verify that:

1. the dental X-ray equipment functions properly and according to applicable standards and legislative requirements;
2. the dental X-ray equipment is installed in a safe environment and is used in a way which provides maximum radiation safety for patients and operators; and
3. the Quality Assurance program is properly implemented and maintained and that the maximum benefits are obtained from the program.

For facilities under federal jurisdiction the responsible agency is the Radiation Protection Bureau, Health Canada, Ottawa, Ontario, K1A 1C1. Dental facilities that fall under provincial/ territorial jurisdiction **MUST** meet the requirements of the responsible agency in their respective provinces. These requirements can be obtained by contacting the appropriate agency listed in Appendix IV.

- **5.2 - OWNER: Existing Dental X-ray Equipment**

Whenever possible and where practical, existing dental X-ray equipment should be upgraded to incorporate the safety and performance features required of new dental X-ray equipment. It should be noted that it is a requirement of the Radiation Emitting Devices Regulations that replacements for any component or subassembly of an X-ray machine, for which a design, construction or performance standard has been specified in the Regulations applicable to the class of X-ray equipment, **MUST** comply with the standards in effect at the time of replacement.

To ensure a reasonable level of protection for patients and staff, all existing dental X-ray equipment **MUST** meet certain basic requirements. These are itemized in the remainder of this section.

- **5.2 - OWNER: General Requirements**

1. *Warning Signs* – The X-ray control panel **MUST** bear a permanent and conspicuous sign prohibiting unauthorized use and warning that hazardous X-radiation is emitted when the equipment is in operation.
2. *Status indicator* – There **MUST** be readily discernible indicators on the control panel that indicate:
 - (i) when the control panel is energized and the machine is ready to produce X-rays, and
 - (ii) when X-rays are produced.

When more than one X-ray tube is controlled by one control panel, there **MUST** be readily discernible indicators, at or near each X-ray tube housing and on the control panel, showing which tube is connected and ready to be energized. There should be an interlock preventing the energizing of more than one X-ray tube at the same time. These indicators can be in the form of lights, light emitting diodes (LEDs) , liquid crystal displays (LCDs) or other.

3. *Indication of loading factor* – For dental X-ray equipment having adjustable loading factors, the control panel **MUST** incorporate electrical meters or other indicators that enable determination of the X-ray tube voltage, X-ray tube current and time, or combinations of these. For equipment having non-adjustable loading factors, permanent marks or labels may be used to indicate these parameters.
4. *Irradiation switch* – There **MUST** be an irradiation switch to start and terminate X-ray production. This switch **MUST** be of a type that requires continuous pressure by the operator to produce X-rays. Where the irradiation switch is a footswitch it **MUST** be so constructed that operation of the X-ray tube cannot occur inadvertently should the footswitch be overturned.

Where the irradiation switch is mounted at the end of a cable, the cable **MUST** be of sufficient length to enable the operator to stand at least 3 meters from the tube housing and the patient. If the switch is in a fixed location, it **MUST** be at least 3 meters from the tube housing.

5. *Controlling timer* – An electronic timing device **MUST** be provided to automatically terminate the irradiation. Mechanical timers **MUST not** be used. The timer **MUST** be designed and constructed in such a way that:
 - (i) it is not possible to energize the X-ray tube without automatic or manual resetting of the timer after each loading;
 - (ii) irradiation cannot be started with the timer set at its zero or OFF position; and
 - (iii) the production of X-rays is automatically terminated after a preset time, preset milliampere-second value, a preset exposure or air kerma value.

6. *Filtration* – There **MUST** be radiation-absorbing filters that provide a degree of attenuation such that the first half-value layer of aluminum is not less than the Ovalue shown in Table 1 for a selected X-ray tube voltage. For other X-ray tube voltages, the half-value layer of the radiation beam **MUST not** be less than the value obtained by linear interpolation from that table.

Table 1
Half-Value Layer
X-ray Tube Voltage (kilovolt)
First Half-Value Layer (millimetre of Al)

50	1.5
60	1.5
70	1.5
71	2.1
80	2.3
90	2.5

7. *Mechanical stability* – The X-ray tube **MUST** be securely fixed and correctly aligned within the tube housing. The X-ray tube housing **MUST** maintain its required position or movement without excessive drift or vibration during operation and **MUST** be supported by mechanical means.

8. *X-ray tube voltage* – The actual peak X-ray tube voltage should not deviate from the indicated or selected value by more than 7%, or by the value specified by the manufacturer. It **MUST** not be possible to set or operate the X-ray tube with the tube voltage below 50 kilovolts (peak).

11. *Linearity* – For any selected X-ray tube voltage within the range of values specified for the equipment, and for any irradiation time greater than 1/20 second, the following relation **MUST** hold:

$$X_1 - X_2 < 0.1 (X_1 + X_2)$$

where X_1 and X_2 are the average values of exposure (kerma) per second, per pulse or per milliampere-second obtained:

- (i) where the X-ray tube current is fixed, at each two settings of irradiation timer not differing by more than a factor of two, or
- (ii) where the irradiation time is fixed, at each two X-ray tube current settings not differing by more than a factor of two.

12. *X-ray tube shielding* – The X-ray tube **MUST** be enclosed within a shielded housing. The housing **MUST** be constructed so that the leakage radiation, measured at a distance of one meter in any direction from the focal spot of the X-ray tube, does not exceed 0.87 mGy (100 mR) in one hour for any specified rating of the tube.

- **5.2 - OWNER: Conventional Dental X-ray Equipment**

1. Applicator –A position- indicating device **MUST** be provided to limit the minimum focal spot to skin distance to not less than 18 centimeters. The applicator **MUST** be an open-ended type. Pointed cone or close- ended applicators **MUST** not be used.
2. Beam limiting device –The primary radiation beam **MUST** be collimated in size at the end of the applicator to a circle not more than 7 centimeters in diameter, or a rectangle of area not more than 38.5 cm² .
3. Controlling timer –The maximum pre-settable irradiation time **MUST not** exceed 5 seconds, or the time required to deliver 50 milliamperere seconds, whichever is shorter.

- **5.2 - OWNER: Panoramic X-ray Equipment**

1. Applicator –A position- indicating device **MUST** be provided to limit the minimum focal spot to skin distance to not less than 15 centimeters.
2. Beam limiting device –The primary radiation beam **MUST** be collimated such that the size of the radiation beam at the image receptor does not exceed any dimension of the scanning slit by more than one- half of that dimension or by more than 2% of the focal spot to image receptor distance, whichever is less.
4. Controlling timer –The maximum presettable irradiation time **MUST not** exceed 25 seconds, or the time required to deliver 250 milliamperere- seconds, whichever is shorter.

- **5.2 - OWNER: Cephalometric X-ray Equipment**

1. Beam limiting device –The size of the primary radiation beam **MUST not** be more than 30 cm in diameter, or 800 cm² in area for a rectangle, at a distance of 1.5 metre, or at the maximum focal spot to image receptor distance, whichever is less. Furthermore, the collimation **MUST** be such that the primary radiation beam is fully intercepted by the film cassette at the focal spot to film distance.

- **6.1 - OWNER: Film processing**

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, to achieve full development of the film.

To ensure proper processing of films, it is necessary to observe the following recommendations:

1. Manufacturers 'recommendations concerning the strength of solution, temperature and time **MUST** be strictly followed to ensure optimum development. An accurate thermometer is essential for adequate processing and, for manual processing, an accurate timer **MUST** be used.
2. Developing solutions **MUST** be replenished as necessary and **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 increased also significantly.
4. Cleanliness is extremely important for reducing film artifacts in both manual and automatic film processing. Proper stainless steel processing tanks complete with water bath and lids **MUST** be used when manual processing is used. With automatic processors, the film transport mechanisms **MUST** be cleaned frequently.
5. Automatic film processors **MUST** be maintained regularly, in accordance with the manufacturers 'instructions, and the temperature and composition of the processing chemicals **MUST** be kept within the specified tolerances.

- **6.2 - OWNER: Darkroom**

The following rules apply to all darkrooms:

1. The room **MUST** be light- tight.
2. The darkroom **MUST** be designed to incorporate a lockable door, double doors or a blackened maze entrance to ensure light- tightness when undeveloped films are being handled.
3. A warning light should be located outside the darkroom, at the entrance, to indicate when the room is in use.
4. Safelights equipped with bulbs of correct intensity **MUST** be provided above the work area within the darkroom. Safelights **MUST** have filters appropriate to meet the specifications of the film used and **MUST** be positioned at the proper distances from work areas. Safelight filters should be checked regularly since they may deteriorate with time or may crack.
5. The darkroom **MUST** be equipped with proper stainless steel processing tanks with water bath and lids, including an accurate thermometer and timing device.

- **6.3 - OWNER:** Film storage container **MUST** be adequately shielded to ensure that excessive irradiation of film by X-rays does not occur.

- **7.1 - OWNER:** All staff members **MUST** understand the goals of the program and **MUST** be committed to the concept.

- **7.1 - OWNER:** To provide accurate and timely diagnosis while minimizing radiation exposure to the patient, the radiogram **MUST** contain all critical information necessary for accurate interpretation.

- **7.3 - OWNER:** Establishment of Administrative Procedures
Responsibility assignments –The owner of the facility is ultimately responsible for the implementation and operation of the Quality Assurance program.

Limits of acceptability of data –Upper and lower limits of acceptability of recorded data **MUST** be defined.

- **7.4 - OWNER:** Radiographic Imaging Quality Control
 1. Any chemicals showing sign of oxidization or sedimentation **MUST** not be used.
 2. Darkroom conditions –The darkroom **MUST** be clean of dirt, dust, and spilled chemical residues. The darkroom **MUST** be light- tight and that proper darkroom lighting used. Guidelines set in section 6.2 should be followed.
 3. Manual processing –Film manufacturers’ recommendations regarding film chemicals, processing temperature and processing time **MUST** be adhered to during manual processing. A thermometer and timer **MUST** always be used. Guidelines set in section 6.1 should be followed. A schedule for periodic replenishment of film chemicals based on the workload and on the type of film used should be prepared.

- **7.5 - OWNER:** It **MUST** be noted that some facilities may require different frequency of testing than suggested.

- **8.0 - OWNER:** Procedures to Reduce Radiation Exposure to Personnel
The procedures outlined in this section are intended to decrease or eliminate radiation exposures to staff and others. To achieve optimum safety, operators of dental X-ray equipment **MUST** make every reasonable effort to keep radiation exposure to themselves and to others below the limits specified in Appendix I.

- **8.1 OWNER:** General Recommendations
 1. A room **MUST** not be used at the same time for more than one radiological investigation.
 2. All persons, other than the patient and those whose presence is essential, **MUST** leave the room when a radiographic examination is carried out.
 3. Personnel **MUST** always keep as far away from the primary radiation beam as practical. Direct radiation exposure to personnel **MUST** not occur. Deliberate irradiation of an individual for training purposes **MUST** never be allowed. Anatomical phantoms of the human head and jaw regions should be provided for student to practice radiography during training courses.
 4. All personnel **MUST** use the protective devices available.
 5. The operation of a X-ray tube should be controlled from the control panel located outside the radiography room or behind a protective barrier. In special circumstances, where the operator is required to control the loading while at the side of the patient, protective clothing **MUST** be worn.
 6. The dental film should be fixed in position with a holding device, whenever possible, otherwise it should be held by the patient. The dental practitioner or other personnel **MUST** not hold the film in place for the patient during the procedure.
 7. When there is a need to support children or weak patients, holding devices should be used. If parents, escorts or other personnel are called to assist, they **MUST** be provided with protective clothing and be positioned to avoid the primary radiation beam. No one **MUST** regularly perform these duties.
 8. An X-ray tube housing **MUST** not be held by hand during operation.
 9. All operators of X-ray equipment, together with personnel who routinely participate in radiological procedures **MUST** wear personnel dosimeters.
 10. The personnel dosimeter **MUST** be worn under the protective clothing.
 11. Energized dental X-ray equipment **MUST** not be left unattended.

12. Where a radiation dose in excess of 5% of the recommended dose limits for radiation workers specified in Appendix I is being received by any one person, an investigation about the causes and appropriate remedial steps **MUST** be taken to improve techniques and protective measures.
 13. Dental X-ray equipment **MUST** only be operated by individuals who have been trained in the safe use of the equipment and the procedures being performed.
- **Appendix I - OWNER:** It **MUST** be noted that the recommended dose limits for radiation workers apply only to radiation exposure resulting directly from their occupation and do not include exposure from other sources, such as medical diagnosis and background radiation.
 - **Appendix I - OWNER:** It is emphasized that any irradiation does involve some degree of risk and although the levels recommended in this Appendix are maximum permitted values, all doses should be kept as low as reasonably achievable and any unnecessary irradiations **MUST** be avoided.
 - **Appendix II - OWNER:** The shielding thicknesses are for a single radiation source. If more than one source irradiates the location of interest, the contribution from each source **MUST** be taken into account in determining the amount of shielding required.
- (2) Any testing of dental X-ray equipment with an extraoral source that is carried out to verify its compliance with the functioning standards set out in subsection (1) shall be conducted under the following conditions:
- (a) the unloaded line voltage **MUST** remain within 1 per cent of its nominal value; and
 - (b) the line voltage **MUST** be regulated in such a manner that it does not vary by more than 6 per cent when the line is fully loaded at the maximum rated line current of the equipment.
- **9.2 - OWNER/OPERATOR:** *Guidelines for Protecting the Patient during Radiographic Examinations*
It is the responsibility of the **operator** and **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 recommendations that follow are intended to provide guidance to the operator and dental practitioner in exercising responsibility towards reduction of radiation exposure to the patient.
1. The operator **MUST** not perform any radiographic examinations not prescribed by the dental practitioner responsible for the patient.
 2. The dose to the patient **MUST** be kept to the lowest practical value, consistent with clinical objectives. To achieve this, techniques appropriate to the equipment available should be used. It is recommended the X-ray loading factors charts be established when using X-ray units which do not have preprogrammed anatomical feature settings. The loading factors chart **MUST** be established after optimizing the film processing procedure.
 3. Fluoroscopy **MUST** not be used in dental examinations.
 4. Dental radiography **MUST** not be carried out at X-ray tube voltages below 50 kilovolts (peak) and should not be carried out at X-ray tube voltages below 60 kilovolts (peak).

5. Dental X-ray equipment should be well maintained and its performance checked routinely. Accurate calibration of the equipment should also be carried out on a regular basis.
 6. The quality of radiograms should be monitored routinely, through a Quality Assurance program, to ensure that they satisfy diagnostic requirements with minimal radiation exposure to the patient.
 7. The patient **MUST** be provided with a shielded apron, for gonad protection, and a thyroid shield, especially during occlusal radiographic examinations of the maxilla. The use of a thyroid shield is especially important in children. The shielded apron and thyroid shield should have a lead equivalence of at least 0.25 mm of lead. In panoramic radiography, since the radiation is also coming from the back of the patient, a conventional lead apron is not adequate and dual (front and back) lead aprons should be worn.
 8. The primary X-ray beam **MUST** be collimated to irradiate the minimum area necessary for the examination.
 9. The primary X-ray beam should be aligned and the patient's head positioned in such a way that the beam is not directed at the patient's gonads and is not unnecessarily irradiating the patient's body.
 10. The fastest film or film- screen combination consistent with the requirements of the examination should be used. The film processing technique should ensure optimum development and should be in accordance with the recommendations given in section 6.1. Sight developing **MUST** not be done.
 11. Dental X-ray films **MUST** be examined with a viewbox specifically designed for this purpose.
 12. For patients, the risk involved in the radiographic examination **MUST** always be weighed against the requirement for accurate diagnosis. Information from the Dental Exposure Normalization Technique (D.E.N.T.) program is used to provide realistic sets of limits.
- **3.2 - X-ray Equipment Operators**
All X-ray equipment **operators** should be certified according to a recognized standard and **MUST** possess qualifications required by any applicable federal, provincial or territorial regulations or statutes. All **operators MUST**:
 1. understand the recommendations of this Safety Code;
 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;
 4. strive to eliminate unnecessary radiographic procedures and reduce to the lowest practical values all patient exposures to radiation; and
 5. participate fully in the established Quality Assurance program for the facility.

A female operator should immediately notify her employer upon knowledge that she is pregnant, in order that appropriate steps may be taken to ensure that her work duties during the remainder of the pregnancy are compatible with the recommended dose limits as stated in *Appendix I*. In general, there is no reason to remove pregnant operators, or other pregnant staff members, from their duties of operating dental X-ray equipment.

- **5.1 - Manufacturer/Vendor/Distributor:** *Newly Acquired Dental X-ray Equipment*
All dental X-ray equipment, and its accessories, sold, imported or distributed in Canada, **MUST** conform to the requirements of the Radiation Emitting Devices Act and the Food and Drugs Act. The requirements, promulgated under these two Acts, are specified in the Radiation Emitting Devices Regulations and the Medical Devices Regulations. The former regulation specifies standards of design, construction and performance, with respect to radiation safety. The latter regulations encompass all other safety considerations and the question of efficacy for all dental X-ray equipment. It is the responsibility of the manufacturer or distributor to ensure that the equipment conforms to the requirements of the regulations.

It **MUST** also be noted that all used dental X-ray equipment, and accessories for such equipment, **MUST** conform to the requirements of the Radiation Emitting Devices Act and Regulations for dental X-ray equipment, when such equipment is being sold, imported or distributed.