Revised: April 2014 EH - OSH

Ministry of Health and Environment

Department of Health

Licensee:	BRL#:	BRD#:
Owner Name by:Print Name		-
Signature of Owner		
Date Received:dd/mm/yyyy		

Dental Cone Beam Computed Tomography (CBCT) License Conditions

A copy of these conditions shall be displayed at each licensed unit in a place readily visible to the public and complete section above by July 1st of every year.

1. **INTRODUCTION**

The use of X-rays in dental radiology is governed by *Health Canada Safety Code 30* entitled "Radiation Protection in Dentistry – Recommended Safety Procedures for the Use of Dental X-Ray Equipment" (Revised in 2000).

Health Canada Safety Code 30 applies to two-dimensional X-ray imaging (i.e. Film, Conventional Radiography, and Digital Radiography) but a number of its radiation protection provisions apply also to Three-Dimensional dental imaging (Cone Beam Computed Tomography, CBCT).

The following conditions on three-dimensional (3D) dental Cone Beam Computed Tomography (CBCT) represent a supplement to *Health Canada Safety Code 30* to include the safety and quality requirements for dental CBCT not covered by the current code.

2. RADIATION SAFETY SHALL BE UNDER THE CONTROL OF A RADIATION SAFETY OFFICER

2.1 A Radiation Safety Officer must be qualified and experienced to work with radiation emitting devices and be in possession of a certificate verifying the completion of a radiation safety course.

Environmental Health – Occupational Safety & Health Metro Building, 6 Hermitage Road. Devonshire FL01 P.O. Box HM 1195. Hamilton HM EX, Bermuda 2.2 A Radiation Safety Officer must be familiar with the Bermuda legislation to radiation and the safety and health legislation as well as the relevant safety codes adopted by the Government of Bermuda. (ie. The Radiation Act 1972, Occupational Safety & Health Act 1982, Occupational Safety & Health Regulations, 2009).

3. JUSTIFICATION OF DENTAL CBCT EXAMINATIONS AND REFERRAL CRITERIA

- 3.1. Dental Cone Beam Computed Tomography (CBCT) examinations should be justified, i.e. the diagnostic benefit to the patient offsets the radiological risks (dose) associated with the X-ray exposure.
- 3.2. Three-Dimensional Dental X-ray CBCT examinations should be prescribed only when the conventional two-dimensional imaging procedures (intra-oral, tomography, panoramic, or cephalometric x-rays) fall short of providing the clinical information for which dental imaging is required.
- 3.3. Only qualified dentists should prescribe dental CBCT examinations.
- 3.4. The referring dentist should provide all necessary clinical information to the CBCT Practitioner.
- 3.5. CBCT examinations are carried out only after a careful review of the history and clinical examination performed on the patient. A CBCT examination should not be repeated on a patient unless clinically justified by a dentist.

4. CBCT FACILITY DESIGN

4.1. Room Design:

a. The X-ray room should be large enough to house the CBCT machine and allow free movement inside.

4.2. **Operating Station**

- **a.** The operator station should preferably be located outside the X-ray room. If inside, additional X-ray shielding in the form of a protective cubicle must be provided to protect the operator.
- **b.** In addition, the operator station should also be such that:
 - The patient and the X-ray room entrance can be clearly seen by the operator during the CBCT procedure
 - The operator can interrupt the scanning procedure in case of emergency stop.

5. **SAFETY AND WARNING SYSTEMS**

5.1. In facilities where:

- **a.** Access to the X-ray room by members of the public (parents accompanying the patient, visitors) and non occupational workers (non X-ray staff) is possible, a warning light indicating that the X-ray beam is energized or "**ON**" should be provided outside the entrance to the CBCT room.
- **b.** Access to the X-ray room is restricted only to occupational workers, the warning light is optional.
- 5.2. Audible links between patient and operator are highly recommended to maintain communication with the patient during the imaging procedure.
- 5.3. Safety features in the CBCT system (e.g. use of password or other restrictive options) should be enabled to prevent the use of a CBCT machine by unauthorized persons.
- 5.4. CBCT exposures should be initiated from outside the CBCT room (operator station outside) or behind a shielded cubicle (operator station inside).
- 5.5. The option of emergency interruption of a CBCT procedure by the operator and the patient should be provided.

6. RADIATION CONTROLLED AREA

- 6.1. The controlled area extends all through the CBCT room.
- 6.2. Only authorized persons are allowed in the controlled area.
- 6.3. A controlled area sign (with the radiation trefoil) should be posted on the CBCT entrance door.

7. RADIATION SHIELDING

- 7.1. The radiation shielding of the walls and the entrance door of the CBCT room should be estimated on the basis of a 7.5 μ Sv/Hr dose rate limit in uncontrolled areas.
- 7.2. The height of the structural shielding shall be at least 2.1 meters (7 ft.).
- 7.3. All other shielding (cubicle, windows), if applicable, shall have lead-equivalent thickness conforming to valid occupational dose limits.
- 7.4. Care shall be taken to ensure that the X-ray exposure levels in occupied areas around, above and below the CBCT room are within the Limits applicable to uncontrolled areas.

8. RADIATION PROTECTION OF PATIENTS

8.1. Optimization of patient doses

The radiation protection of patients should be optimized; i.e. achieving an acceptable X-ray image quality at the lowest possible dose (ALARA principle for patients).

In this respect, the following parameters should be optimized:

- Volume imaged: Smallest volume compatible with the clinical situation
- kVp and mAs: Should be adapted to each clinical application and patient
- Image Resolution: Use low dose option
- Image projections: Select the option of reduced number of projections

9. PATIENT DOSE METRICS

- 9.1. For the purpose of monitoring patient exposure, the Kerma-Area-Product (KAP) is recommended as the reference dose quantity for dental CBCT.
- 9.2. The symbol of Kerma-Area-Product is PKA in units of mGy.cm2, as defined by the International Commission on Radiation Units and Measurements (ICRU).

10. **DOSE REFERENCE LEVELS**

- 10.1. In the absence of national or local *Dose Reference Levels* (DRL), it is recommended to adopt a guidance level for all dental CBCT imaging procedures based on the existing experience. The guidance level will remain valid until the establishment of DRL values.
- 10.2. CBCT patient dose surveys should be conducted to develop Dose Reference Levels for different dental CBCT examinations.
- 10.3. Dose Reference Levels for pediatric patients shall be clearly distinguished from those of adults.

11. PREGNANT PATIENTS

- 11.1. A warning notice for pregnant patients shall be posted at the facility reception, changing room and other relevant locations to attract the attention of female patients.
- 11.2. Female patients of child bearing age shall be asked about pregnancy prior to the CBCT exposure.
- 11.3. Although head examinations do not result in any significant fetal dose, it is recommended to consider additional protection of the fetus whenever it is practically possible.

12. <u>DENTAL CBCT EQUIPMENT PERFORMANCE TESTING</u>

12.1. Acceptance Tests

- New CBCT installations should undergo acceptance testing to ensure that the equipment performance is in agreement with the manufacturer's technical specifications.
- <u>Department of Health Occupational Safety & Health Office will review and witness testing</u>
- The outcome of the acceptance tests shall determine the level of compliance of the equipment. The results of the acceptance tests shall be saved as a reference (baseline data) for future Quality Control (QC) evaluations.

12.2. Periodical Testing

- CBCT equipment should undergo periodical quality control tests to ensure that the performance of the machine has not significantly deteriorated and remained within acceptable margins.
- The Quality Control program will include the following parts:
 - o X-ray tube: X-ray beam parameters
 - Patient Dose Metric: (Kerma-Area Product, KAP)
 - Image quality: Quantitative assessment
 - Display screen: Luminance (Cd/m2)
 - Viewing room: Illuminance (Lux)
- The protocols and periodicity of the quality control tests shall be defined by the Department of Health - Occupational Safety & Health Office.
- The periodical quality control tests shall be conducted by qualified specialists such as Biomedical Engineers, Health Physicists, and Medical Physicists.

12.3. **TESTING TOOLS**

 Due to the diversity of CBCT machines, it is recommended to acquire and use the manufacturer's image quality test tools for the daily checks by the operator.

13. TRAINING OF CBCT PERSONNEL

13.1. The clinical and paramedical personnel involved with Cone Beam Computed Tomography should have sufficient theoretical and practical training on 3D dental imaging validated by Bermuda Dental Board

14. **RECORDS**

For patient exposure monitoring, the following records should be kept for each CBCT procedure:

- Type of CBCT examination
- Imaging view settings
- Kerma-Area-Product (KAP, mGy.cm2)

15. **REFERENCES**

Health Canada Safety Code 30 – Radiation Protection in Dentistry

http://www.hc-sc.gc.ca/ewh-semt/alt_formats/hecs-sesc/pdf/pubs/radiation/99ehd-dhm177/99ehd-dhm177-eng.pdf

• Radiation Protection: Cone Beam CT (CBCT) for Dental and Maxillofacial radiology – Evidence Based Guidelines, v 2.0, final draft SEDENTEXCT, 2011

www.sedentexct.eu

• KCARE/UK- Evaluation Report - Dental Cone Beam Tomography (CBCT) Systems CEP 10048, March 2010

http://www.kcare.co.uk

Leeds Test Objects – Medical Imaging Phantoms – CBCT – 2011

www.leedstestobjects.com

 Recommendations for the Design of X-ray facilities and the quality assurance of Dental Cone Beam CT Systems, HPA-RPD-065 – March 2010 – Health Protection Agency – UK

http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1267551245480