

## Appendix 6 - Compliance Verification Checklist Dental Cone Beam CT X-ray Equipment

In accordance with:

Safety Code 30: "Radiation Protection in Dentistry – Recommended Safety Procedures for the Use of Dental X-ray Equipment " published by Health Canada (2000),

Safety Code 35: "Safety Procedures for the Installation Use and Control of X-ray Equipment in Large Medical Radiological Facilities" published by Health Canada (2009)

Radiation Emitting Device Regulations (Nov 4, 2009), and

Radiation Protection Act (November 1, 2010)

| Item No. | Compliance Item Description<br>General Information & Facility Requirements   | Reference                     | Yes | No | N/A |
|----------|--|-------------------------------|-----|----|-----|
| 1.       | There is an existing certificate.  |                               |     |    |     |
| 2.       | If (1) is "yes", the certificate must be posted in the room or nearby (except mobile).   |                               |     |    |     |
| 3.       | For mobile: If (1) is "yes", where is the certificate?   |                               |     |    |     |
| 4.       | The radiation shielding of the room is adequate and meets regulatory standards.  |                               |     |    |     |
| 5.       | The X-ray warning signs are posted on the entrance doors to the X-ray room.  |                               |     |    |     |
| 6.       | Protective apparel is available to patient and any individual in the irradiation area.   |                               |     |    |     |
| 7.       | A quality assurance program exists for the equipment   | SC30: 7.5.3<br>RPA: 14(1)-(2) |     |    |     |
| 8.       | A preventive maintenance program exists for the equipment.   | RPA: 14(1)-(2)                |     |    |     |
| 9.       | A scattered radiation profile is provided for information.   |                               |     |    |     |
| 10.      | The radiation equipment has been approved for use in Canada  | SC30: 5.1                     |     |    |     |
|          | <b>Radiation Protection</b>  |                               |     |    |     |
| 11.      | I. Shielding and Protection<br>1. 20 mSv per year for radiation worker in controlled areas<br>2. 1 mSv per year for members of the public in uncontrolled areas  | SC30: 4.1(i)<br>SC30: 4.1(ii) |     |    |     |
| 12.      | Rooms which can be accessed from public areas should be equipped with a self-closing door.   | SC35: B1.2.2.1                |     |    |     |
| 13.      | The X-ray equipment should 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.   | SC35: B1.2.2.4                |     |    |     |
| 14.      | The operator is not exposed to the primary radiation beam.   | SC30: 4.2.1                   |     |    |     |
| 15.      | The operator keeps a distance of at least 3 metres from the X-ray tube and the patient. If this is not possible, an adequately shielded barrier, which allows observation of the patient, must be provided for the | SC30: 4.2.1                   |     |    |     |

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|  | operator to stand behind during radiography.  |  |  |  |  |
| 16.  | The primary radiation beam and scattered radiation are absorbed as close as possible to the source.   | SC30: 4.2.4                                |  |  |  |
| 17.  | The primary radiation beam is always directed towards a shielded or unoccupied area.  | SC30: 4.2.5                                |  |  |  |
| 18.  | All personnel must fully use all protective devices available.  | SC30: 8.1.4                                |  |  |  |
| 19.  | All operators of X-ray equipment, together with personnel who routinely participate in radiological procedures must wear personal dosimeters under their protective clothing.   | SC30: 8.1.9 & 8.1.10                       |  |  |  |
| 20.  | Radiation protection surveys have been performed as required.   | SC30: 4.2.7                                |  |  |  |
| 21.  | Dental Radiography<br>(a) must not be carried out at X-ray tube voltages below 50 kilovolts (peak);<br>(b) should not be carried out at X-ray tube voltages below 60 kilovolts (peak).  | SC30: 9.2.4                                |  |  |  |
| 22.  | Protective apparel<br>(a) the patient must be provided with a shielded apron, for gonad protection, and a thyroid shield;<br>(b) the apparel should have adequate lead equivalency: (0.25 mm for gonads and thyroid shields and preferably 0.5 mm for aprons);<br>(c) in panoramic radiography, dual (front and back) lead aprons should be worn;<br>(d) in CT radiography, dual (front and back) lead aprons should be worn.                     | SC30: 9.2.7                                |  |  |  |
| <b>General Requirements of the Equipment</b> |   |  |  |  |  |
| 23.  | II. Labelling<br>For Generator<br>(a) the name of the manufacturer,<br>(b) the model designation,<br>(c) the serial number,<br>(d) the date of manufacture, and<br>(e) the country of manufacture.<br><br>For X-ray Tube<br>(a) the name of the manufacturer,<br>(b) the model designation,<br>(c) the serial number,<br>(d) the country of manufacturer,<br>(e) specification of the minimum permanent inherent filtration (expressed in mm Al). | REDR: II 5.(1)(c)<br><br>REDR: II 5.(1)(d) |  |  |  |

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| 24. | <p>III. Warning Signs</p> <p>The X-ray control panel must bear a permanent, visible and legible sign warning that hazardous X-rays are emitted when the equipment is in operation and prohibit unauthorized use.</p>   | SC30: 5.2.1.1                                     |  |  |  |
| 25. | <p>IV. Markings</p> <p>All controls, meters, lights and other indicators relevant to the operation of the equipment must be readily discernible and clearly labelled or marked as to function.</p>   | SC35: B2.5.1.2                                    |  |  |  |
| 26. | <p>V. Mechanical Stability</p> <p>1. The X-ray tube must be securely fixed and correctly aligned within the CT gantry.</p> <p>2. The X-ray source assembly must maintain their required positions without excessive drift or vibration during operation.</p>   | SC35: B.2.5.1.3                                   |  |  |  |
| 27. | <p>VI. Indicators and Indicator Lights</p> <p>1. There must be readily discernible, separate indicators on the control panel that indicate:</p> <p>(a) when the control panel is energized and the machine is ready to produce X-rays;</p> <p>(b) when X-rays are being produced.</p>  | SC30: 5.2.1.2                                     |  |  |  |
| 28. | <p>VII. Indication of Loading Factors</p> <p>1. Dental X-ray equipment having adjustable loading factors must incorporate meters or other indicators on the control panel that enable determination of the X-ray tube voltage, X-ray tube current and time, or combination of these.</p> <p>2. For equipment having non-adjustable loading factors, permanent marks or labels may be used to indicate these parameters.</p> <p>3. All CT conditions (section thickness, pitch factor etc...) of operation during a scan series must be indicated prior to the initiation of a scan or scan series.</p> | SC30: 5.2.1.3<br>SC30: 5.2.1.3<br>SC35: B2.5.4.2  |  |  |  |
| 29. | <p>VIII. Irradiation Control and Movement Termination</p> <p>1. There must be an irradiation switch to initiate and terminate X-ray production.</p> <p>2. Initiation or continuation of irradiation is only possible from the control panel.</p> <p>3. An emergency stop switch must be in place on or near the patient support and/or gantry to immediately terminate the motion of the equipment and the emission of X-rays.</p>   | SC30: 5.2.1.4<br>SC35: B2.5.4.1<br>SC35: B2.5.4.3 |  |  |  |
| 30. | <p>IX. Controlling Timer</p> <p>1. An electronic timing device must be provided to automatically terminate the irradiation. Mechanical timers must not be used.</p>  | SC30: 5.2.1.5                                     |  |  |  |

|                         | <p>2. The timer must be designed and constructed in such a way that:</p> <p>(a) it is not possible to energize the X-ray tube without automatic or manual resetting of the timer after each loading;</p> <p>(b) irradiation cannot be started with the timer set at its zero or OFF position;</p> <p>(c) the production of X-rays is automatically terminated after a preset time, milliampere-second value, or exposure value.</p>  |                         |                                   |    |     |    |     |    |     |    |     |     |     |     |     |                             |  |  |  |
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|                         | <b>Equipment Performances</b>  |                         |                                   |    |     |    |     |    |     |    |     |     |     |     |     |                             |  |  |  |
| 31.                     | <p>X. X-ray Tube Shielding</p> <p>(1) The X-ray tube must be enclosed in a shielded housing.</p> <p>(2) The shielding of the housing must be such that the leakage radiation from the X-ray source assembly shall not exceed an air kerma rate of 1.0 mGy/h at a distance of 1 m away from the focal spot, when operated at the nominal X-ray tube conditions of loading corresponding to the maximum specified energy input in one hour and, when the equipment is not in the loading state, 20 µGy/h at a distance of 5 cm from any accessible surface.</p>  | SC35: B2.5.1.8          |                                   |    |     |    |     |    |     |    |     |     |     |     |     |                             |  |  |  |
| 32.                     | <p>XI. X-ray Beam Filtration</p> <p>There must be radiation-absorbing filters that provide a degree of attenuation such that the first Half-Value Layer (HVL) of aluminum is not less than the values shown below for a selected X-ray tube voltage. For other X-ray tube voltages, the HVL of the radiation beam must be calculated by linear interpolation from that table.</p> <table border="0"> <thead> <tr> <th>X-ray Tube Voltage (kV)</th> <th>Half-Value Layer of Aluminum (mm)</th> </tr> </thead> <tbody> <tr> <td>60</td> <td>1.9</td> </tr> <tr> <td>70</td> <td>2.1</td> </tr> <tr> <td>80</td> <td>2.4</td> </tr> <tr> <td>90</td> <td>2.7</td> </tr> <tr> <td>100</td> <td>3.0</td> </tr> <tr> <td>110</td> <td>3.4</td> </tr> </tbody> </table> | X-ray Tube Voltage (kV) | Half-Value Layer of Aluminum (mm) | 60 | 1.9 | 70 | 2.1 | 80 | 2.4 | 90 | 2.7 | 100 | 3.0 | 110 | 3.4 | SC35: B2.5.4.5<br>(Table 9) |  |  |  |
| X-ray Tube Voltage (kV) | Half-Value Layer of Aluminum (mm)  |                         |                                   |    |     |    |     |    |     |    |     |     |     |     |     |                             |  |  |  |
| 60                      | 1.9  |                         |                                   |    |     |    |     |    |     |    |     |     |     |     |     |                             |  |  |  |
| 70                      | 2.1  |                         |                                   |    |     |    |     |    |     |    |     |     |     |     |     |                             |  |  |  |
| 80                      | 2.4  |                         |                                   |    |     |    |     |    |     |    |     |     |     |     |     |                             |  |  |  |
| 90                      | 2.7  |                         |                                   |    |     |    |     |    |     |    |     |     |     |     |     |                             |  |  |  |
| 100                     | 3.0  |                         |                                   |    |     |    |     |    |     |    |     |     |     |     |     |                             |  |  |  |
| 110                     | 3.4  |                         |                                   |    |     |    |     |    |     |    |     |     |     |     |     |                             |  |  |  |
| 33.                     | <p>XII. Radiation Output Reproducibility</p> <p>For any combination of operating loading factors, the coefficient of variation of any ten consecutive irradiation measurements, taken at the same source to detector distance within a time period of one hour, is no greater than 0.05. The coefficient of variation is the ratio of the standard deviation to the mean value of a series of measurements calculated by using the following equation:</p> $C = \frac{S}{\bar{X}} = \frac{1}{\bar{X}} \left[ \frac{\sum_{i=1}^n (X_i - \bar{X})^2}{n-1} \right]^{1/2}$   | SC30: 5.2.1.8           |                                   |    |     |    |     |    |     |    |     |     |     |     |     |                             |  |  |  |

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|     | where C is the coefficient of variation, S is the estimated standard deviation, $X_i$ is the value of the $i$ th measurement, $\bar{X}$ is the mean value of the measurements, and n is the number of measurements.  |  |  |  |  |
| 34. | <p>XIII. Radiation Output Linearity</p> <p>For any preselected value of X-ray tube voltage, within an applicable range, and for any irradiation time greater than 1/20 second, the quotient of the average air kerma measurement divided by the indicated current time product obtained at two applicable settings must not differ by more than 0.10 times their sum, that is,</p> $  X_1 - X_2   \leq 0.10 ( X_1 + X_2 )$ <p>where <math>X_1</math> and <math>X_2</math> are quotients of the average air kermas measurement divided by the current time product at two applicable settings of X-ray tube current (fixed irradiation time) or irradiation timer (fixed tube current). Both settings must not differ by more than a factor of two.</p>   | SC30: 5.2.1.11   |  |  |  |
| 35. | <p>XIV. X-ray Tube Voltage</p> <ol style="list-style-type: none"> <li>1. 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.</li> <li>2. It must not be possible to set or operate the X-ray tube with the tube voltage below 50 kilovolts (peak).</li> </ol>   | SC30: 5.2.1.9  |  |  |  |
| 36. | <p>XV. Computed Tomography</p> <ol style="list-style-type: none"> <li>1. The performance of the CT X-ray equipment is evaluated using phantoms of proper design.</li> <li>2. The dose delivered by the CT X-ray system is determined using a CT dosimetry phantom.</li> <li>3. Base-line dose and image information required to assess the Continuing performance of the CT X-ray system has been obtained from the manufacturer or has been established by a qualified medical physicist.</li> <li>4. In normal use the information indicating the orientation of the displayed image with respect to the patient must be displayed with each image.</li> <li>5. Light Field <ol style="list-style-type: none"> <li>(a) A light field must be provided for marking the tomographic section or reference plane.</li> <li>(b) The light must be visible under ambient light conditions of up to 500 lx.</li> <li>(c) The width of the light field must not exceed 3 mm, measured in the centre of the gantry opening, and the coincidence of the centre of the light field and the centre of the tomographic plane must be</li> </ol> </li> </ol> | <p>SC35: C3.6.3<br/>Table 22</p> <p>SC35: B2.5.5.2</p> <p>SC35: B2.5.5.2</p> <p>SC35: B2.5.4.9</p> <p>SC35: B2.5.4.7</p> |  |  |  |

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|  | <p>within 2 mm.</p> <p>6. The minimum focal spot to skin distance must be at least 15 cm.</p> <p>7. The collimation must be such that the primary radiation beam is fully intercepted by the detector at the focal spot to film distance.</p> | <p>SC35: B2.5.4.4</p> <p>SC30: 5.2.4</p> |  |  |  |
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