PROPOSED RULE MAKING

CR-102 (June 2004)
(Implements RCW 34.05.320)
Do NOT use for expedited rule making

Agency: Department of Health

Preproposal Statement of Inquiry was filed as WSR 09-16-141 ; or
Expedited Rule Making--Proposed notice was filed as WSR ; or
Proposal is exempt under RCW 34.05.310(4).

Title of rule and other identifying information: (Describe Subject)
Chapter 246-225A WAC Rules and Regulations -- Radiation Safety and Diagnostic Imaging Quality Standards for Dental Facilities

Hearing location(s):
Washington State Department of Health
111 Israel Road SE
Tumwater, WA 98501
Town Center 3, Room 123

Date: July 6, 2011
Time: 2:00 p.m.

Submit written comments to:
Name: Phyllis Barney
Address: POB 47827
Olympia, WA 98504-7827
Website: http://www3.doh.wa.gov/policyreview/
fax 360-236-2255 by (date) 07/06/2011

Assistance for persons with disabilities: Contact Sharon Grundhoffer by 06/29/2011
TTY (800) 833-6388 or () 711

Date of intended adoption: 07/07/2011
(Note: This is NOT the effective date)

Purpose of the proposal and its anticipated effects, including any changes in existing rules:
The proposed rule establishes criteria for the use of hand-held dental X-ray equipment. It amends existing requirements for quality assurance testing, safelights, and film and screen use. It includes editorial changes for clarification and consistency with existing requirements.

Reasons supporting proposal:
At the request of stakeholders, the department reviewed the regulations regarding the use of hand-held dental X-ray equipment. Based on this review, the department determined this equipment can be used safely when specific dose rate criteria and operator requirements are met. The proposed rule changes would allow use of hand-held dental X-ray equipment under the specified criteria.

Statutory authority for adoption:
RCW 70.98.050

Statute being implemented:
RCW 70.98.080

Is rule necessary because of a:
Federal Law? Yes  No
Federal Court Decision? Yes  No
State Court Decision? Yes  No
If yes, CITATION:

DATE 05/23/11

NAME (type or print)
Mary C. Selecky

SIGNATURE

TITLE
Secretary

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: May 24, 2011
TIME: 3:17 PM
WSR 11-12-026

(COMPLETE REVERSE SIDE)
Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters:
None.

<table>
<thead>
<tr>
<th>Name of proponent:</th>
<th>Department of Health</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Name of agency personnel responsible for:</th>
<th>Office Location</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drafting................ Andrew Thatcher</td>
<td>111 Israel Road SE Tumwater, WA 98501</td>
<td>360-236-3231</td>
</tr>
<tr>
<td>Implementation.... Andrew Thatcher</td>
<td>111 Israel Road SE Tumwater, WA 98501</td>
<td>360-236-3231</td>
</tr>
<tr>
<td>Enforcement........ Andrew Thatcher</td>
<td>111 Israel Road SE Tumwater, WA 98501</td>
<td>360-236-3231</td>
</tr>
</tbody>
</table>

Has a small business economic impact statement been prepared under chapter 19.85 RCW?

☐ Yes. Attach copy of small business economic impact statement.

☐ No. Explain why no statement was prepared.
A small business economic impact statement was not prepared. The proposed rule would not impose more than minor costs on businesses in an industry.

Is a cost-benefit analysis required under RCW 34.05.328?

☐ Yes A preliminary cost-benefit analysis may be obtained by contacting:
Name: Phyllis Barney
Address: Office of Radiation Protection
PO Box 47827
Olympia, WA 98504-7827
phone 360-236-3239
fax 360-236-2266
e-mail phyllis.barney@doh.wa.gov

☐ No: Please explain:
Small Business Economic Impact Statement (SBEIS) Determination  
Chapter 19.85 RCW, Regulatory Fairness Act

Section 1. What is the scope of the proposed rule package?

This proposed rule establishes criteria for the use of hand-held dental X-ray equipment. It amends existing requirements for quality assurance testing, safelights, and film and screen use. It also proposes new definitions and editorial changes for clarification and consistency with existing requirements.

At the public hearing for the original adoption of Chapter 246-225A WAC, Radiation Safety and Diagnostic Image Quality Standards for Dental Facilities, the Department of Health (department) agreed to review the regulations regarding the use of hand-held dental X-ray equipment. Currently these devices are only allowed under a variance. The department’s recent testing of hand-held X-ray equipment from several manufacturers determined this equipment can be used safely when specific dose rate criteria and operator requirements are met. These proposed changes promote better patient care and lower cost in Washington without posing a higher risk of harm to the operator or patient.

Based on inspection results and feedback from registrants and stakeholders, the department proposes to modify the requirement for weekly quality assurance (QA) testing of dental X-ray film processors. Chapter 246-225A WAC currently requires all dental registrants to perform weekly QA testing. However, department inspections show the majority of dental registrants process film effectively, and do not need to perform quality assurance testing. The proposed QA requirements apply only to those facilities with inadequate film processing.

The current text is very specific about wattage and placement of safelights used in dental darkrooms. Improper bulb wattage or placement could create fogging of the film which detracts from the diagnostic quality and requires more exposure to achieve an adequate image. Because image clarity is affected by multiple factors including bulb wattage and placement, light leaks into the darkroom, and lights from equipment in the darkroom, the proposed rule replaces prescriptive bulb requirements with performance based requirements for image clarity.

The proposed rule also adds requirements for film and screen use. Some dental facilities continue to use damaged or dirty screens, film that is not compatible with the screens, or film beyond its expiration date. This can result in poor image quality. These discrepancies are addressed during inspections under the general authority in WAC 246-225-020(2)(L). The proposed rule adds clarity to Chapter 246-225A WAC.
Section 2. Which businesses are impacted by the proposed rule package? What are their North American Industry Classification System (NAICS) codes? What are their minor cost thresholds?

<table>
<thead>
<tr>
<th>NAICS Code (4, 5 or 6 digit)</th>
<th>NAICS Business Description</th>
<th># of businesses in WA</th>
<th>Minor Cost Threshold = 1% of Average Annual Payroll</th>
<th>Minor Cost Threshold = .3% of Average Annual Receipts</th>
</tr>
</thead>
<tbody>
<tr>
<td>6212</td>
<td>Office of Dentists</td>
<td>3,223</td>
<td>$3,150</td>
<td>$2,351</td>
</tr>
</tbody>
</table>

Section 3. What is the range of cost per business of the proposed rule?

<table>
<thead>
<tr>
<th>Cost Category</th>
<th>Description</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reporting</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Record Keeping</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Training</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Professional Services (e.g.,</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>engineers, lawyers)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Equipment (type)</td>
<td>X-Ray screen ($80 - $155/screen)</td>
<td>$125.00</td>
</tr>
<tr>
<td>Supplies (type, amount)</td>
<td>X-ray film ($25 - $40/box)</td>
<td>$35.00</td>
</tr>
<tr>
<td>Labor (show hours multiplied by</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>cost per hour)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Administration</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Lost Sales or Revenue</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Total Average Cost</td>
<td></td>
<td>$160.00</td>
</tr>
</tbody>
</table>

Section 4. Does the rule impose more than minor costs on impacted businesses?

Average cost per business $160.00 (from Section 3)
Minor cost threshold- 1% payroll $3,150 (from Section 2)
Minor cost threshold- 3/10% of receipts $2,351 (from Section 2)

Does the average cost per business exceed both of the minor cost thresholds? (Yes or No)
Section 5. Does the rule have a disproportionate impact on small businesses?

<table>
<thead>
<tr>
<th>Cost Category</th>
<th>Small businesses¹</th>
<th>All Large businesses</th>
<th>Largest 10% of “Large” businesses²</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. Number of businesses (NAICS-Minor Cost Threshold Spreadsheet on Rules Webpage)</td>
<td>3,217</td>
<td>6</td>
<td>1</td>
<td>3,224</td>
</tr>
<tr>
<td>II. Cost per business (A+B+C)</td>
<td>$160.00</td>
<td>$160.00</td>
<td>$160.00</td>
<td>$515,840.00</td>
</tr>
<tr>
<td>A. Reporting</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>B. Record Keeping</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>C. Compliance Costs</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C1. Professional Services</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>C2. Equipment</td>
<td>$125.00</td>
<td>$125.00</td>
<td>$125.00</td>
<td>$382,500</td>
</tr>
<tr>
<td>C3. Supplies</td>
<td>$35.00</td>
<td>$35.00</td>
<td>$35.00</td>
<td>1,152.00</td>
</tr>
<tr>
<td>C4. Labor</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>C5. Administration</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>C6. Lost Sales or Revenue</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>C7. Training</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>C8. Other</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>III. Total Costs (I*II)</td>
<td>$514,720.00</td>
<td>$960.00</td>
<td>$160.00</td>
<td>$515,840.00</td>
</tr>
<tr>
<td>IV. Number of employees per business (NAICS-Minor Cost Threshold Spreadsheet on Rules Webpage)</td>
<td>49</td>
<td>99</td>
<td>175</td>
<td></td>
</tr>
<tr>
<td>V. Total number of employees (I*IV)</td>
<td>157,633</td>
<td>594</td>
<td>175</td>
<td>158,402</td>
</tr>
<tr>
<td>VI. Cost of rule per employee (III/V)</td>
<td>$3.27</td>
<td>$1.62</td>
<td>$0.91</td>
<td>$3.25</td>
</tr>
</tbody>
</table>

Is the average cost per employee for small businesses more than the average cost per employee for the largest businesses? (Yes or No) If it is, we will have to show how we mitigate this disparity, if possible.

¹ When estimating costs for small businesses, if you think that there will be a difference in costs for different sized small businesses (e.g., 1-5, 6-20, 21-50, etc.), you may want to provide costs estimates for the different size categories.
² The statute requires us to compare the cost for the average small business compared to the cost for 10% of the “largest” large businesses. You may want to estimate costs for all large businesses in addition to the subset of largest 10% of large businesses.
AMENDATORY SECTION (Amending WSR 08-14-074, filed 6/26/08, effective 7/27/08)

WAC 246-225A-010 Definitions. (As used in this chapter, the following definitions apply.) The definitions in this section apply throughout this chapter unless the context clearly requires otherwise. 

1. "Artifact" means an undesirable optical density or blemish on a radiographic image that detracts from the diagnostic information.

2. "Barrier" (see "protective barrier").

3. "Beam" (see "X ray").

4. "Beam-limiting device," sometimes called a collimator or cone, means a device that controls the size of the X-ray field.

5. "Cephalometric" means X-ray imaging specific to the human head and jaw.

6. "Control panel" means the part of the X-ray system where the switches, knobs, pushbuttons, and other hardware necessary to operate the X-ray system are located.

7. "CR (computed radiography)" means creating an X-ray image using plates consisting of a special phosphor that when exposed to radiation and then processed by a scanner, provides the information to a computer for display and manipulation.

8. "CT (computed tomography)" means creating a cross-sectional X-ray image generated by an X-ray source and detector moving around the patient's body.

9. "Dead-man button" means an X-ray exposure button designed so that it can only be operated by continuous pressure on the button by the operator, and when released before the preset exposure time will stop the exposure.

10. "Department" means the department of health, which is the state radiation control agency under chapter 70.98 RCW.

11. "Detector" means a device capable of receiving and recording an X-ray image.

12. "Diagnostic source assembly" means the combination of the tube housing assembly and the collimator.

13. "Direct scattered radiation" means radiation discharged in a straight line from the object being radiographed.

14. "DR (direct digital radiography)" means creating an X-ray image by sending signals directly from a solid state detector to a computer for display and manipulation.

"Direct scattered radiation" means radiation discharged in a
straight line from the object being radiographed.)

(15) "Exposure," as the context implies, means:
(a) The number of electrons, measured in coulombs per kilogram of air, released through the ionization of air molecules by electromagnetic radiation; (and) or
(b) An occupational worker or patient being subjected to radiation either directly or indirectly.

(16) "Extra-oral radiography" means creating a film or digital X-ray image on an image receptor placed outside the mouth. Examples include panoramic and cephalometric X rays.

(17) "Filter" means material, such as copper or aluminum, placed in the useful beam of the X ray to block selected energies, and in a safelight to block light that could fog the X-ray film.

(18) "Floor plan" means a drawing of the X-ray room, along with its dimensions, identification of adjacent areas and occupiable space above and below.

(19) "Focal spot" means the area on the anode end of the X-ray tube bombarded by the electrons accelerated from the cathode and from which the useful X-ray beam begins.

(20) "Grid" means a device placed between the patient and the image receptor in extra-oral radiography that reduces scattered radiation that would decrease the quality of the image being created.

(21) "Hand-held" (see "X-ray system").

(22) "Healing arts screening" means using X-ray equipment without an order by a licensed practitioner on an individual who does not have a known or diagnosed disease or symptom to learn if the individual may have an indication of ill health.

(23) "HVL (half-value layer)" means the thickness of material that reduces the intensity of radiation to one-half of its original value.

(24) "Image receptor" means a device that transforms an X-ray beam into a visible film or digital for image processing.

(25) "Intra-oral radiography" means creating a film or digital X-ray image on an image receptor placed inside the mouth.

(26) "kV (kilovolt)" means the unit used to measure electrical energy.

(27) "kVp (kilovolts peak)" means the highest possible voltage across the X-ray tube during an exposure (see also "peak tube potential").

(28) "Leakage radiation" means radiation coming from the X-ray tube, other than the useful X-ray beam.

(29) "Leakage technique factors" means the technique factors associated with the tube housing assembly that are used to measure leakage radiation. They are defined as the maximum rated peak tube potential and the maximum rated continuous tube current at the maximum peak tube potential.

(30) "Licensed practitioner" means an individual licensed to practice dentistry under chapter 18.32 RCW.

(31) "mA (milliampere)" means the unit used to measure
electrical current in an X-ray tube.

(32) "mA*s (milliampere second (((mA*s)))" means the product of the electrical current in the X-ray tube in (((milliampere))) mA and the time of exposure in seconds.

(33) "Mobile ((equipment)))" (see "X-ray system").

(34) "Operator" means a person working under the direction of a licensed practitioner to operate X-ray equipment and who has been properly trained according to WAC 246-225A-020.

(35) "Operatory" means a room in which dental health care procedures are performed.

(36) "Peak tube potential" means the maximum voltage in the X-ray tube during an exposure.

(37) "Portable ((equipment))" (see "X-ray ((equipment)) system").

(38) "Position-indicating device" means a device on X-ray equipment that shows where the X-ray beam will be directed and establishes the distance from the X-ray tube to the patient's body. The device may or may not incorporate or serve as a beam-limiting device.

(39) "Primary beam" (see "useful beam").

(40) "Primary protective barrier" means the material placed in the useful beam, beyond the patient and image receptor, to reduce remnant primary beam exposure.

(41) "Protected area" means a space for X-ray equipment operators that is shielded so that X-ray exposures are reduced enough to meet the exposure limits of WAC 246-221-010 (Occupational dose limits for adults) and WAC 246-220-007 (Statement of philosophy). In addition, the space must have no exposure to direct scattered radiation.

(42) "Protective apron" means a garment made of radiation absorbing materials used to reduce a person's radiation exposure.

(43) "Protective barrier" means a structure made of radiation absorbing material used to reduce radiation exposure.

(44) "Quality assurance" means a program designed to produce high quality X-ray images at minimal cost and with minimal patient exposure to radiation.

("Quality control" means the regular testing of X-ray equipment and associated equipment, such as processors, to verify that the equipment is working properly. Controls include performing routine tests of the diagnostic X-ray imaging system such as X-ray beam output, viewing X-ray test images, and continually adjusting the performance of the X-ray equipment and processor to an optimal and consistent level.)

(45) "Quick developer" means small-volume chemistry designed to process dental intra-oral film in less than a minute.

(46) "Radiation safety" means ways to protect patients and staff from unnecessary radiation exposure. Safety measures may include patient exposure reduction, image quality improvement, diagnostic imaging system quality assurance, radiation measurements, dose evaluations, compliance with state and federal regulations, and related issues.

(47) "Radiographic" means the production of an image created when an X-ray pattern exits an X-rayed object.
(48) "Radiography" means a way of creating a permanent film or digital image using X rays.
(49) "Recording" means creating a permanent image, on film or in a computer, from an X-ray exposure.
(50) "Registrant" means the owner or controller of the radiation equipment who is responsible for the safe operation of the radiation equipment in accordance with this chapter and chapter 70.98 RCW.
(51) "Registration" means providing required information and continuing contact with the department by any person possessing a radiation machine in accordance with chapter 246-224 WAC, Radiation protection--Radiation machine assembly and registration.
(52) "Remnant primary beam" means the part of the useful beam that completely passes through the patient and image receptor.
(53) "Ring-detector type CT" means computed tomography performed with a fan-shaped beam that generates image slices of anatomy rather than using a cone-shaped beam creating a volumetric picture.
(54) "Safe light" means a lamp with a filter that is used in an X-ray darkroom to provide enough light to see, but not enough to fog the film.
(55) "Scattered radiation" means radiation that has changed direction, or generated other radiation as it impacts or passes through matter (see also "direct scattered radiation").
(56) "Scram button" means a large, prominently displayed button, mounted in an X-ray operator's area to allow quick termination of an X-ray exposure in case of an emergency.
(57) "Secondary protective barrier" means an object or material sufficient to reduce stray radiation to the required degree as stated in chapter 246-221 WAC (Radiation protection standards).
(58) "SID (source-to-image-receptor distance ((SID)))" means the distance from the focal spot in the X-ray tube to the center of the surface of the image receptor.
(59) "Source" means the focal spot of the X-ray tube.
(60) "SSD (source-to-skin distance ((SSD)))" means the distance between the focal spot of the X-ray tube and the nearest point on the patient's skin where the primary beam enters.
(61) "Stationary ((equipment))" (see "X-ray system").
(62) "Stray radiation" means the sum of leakage and scattered radiation.
(63) "Technique chart" means a written instruction or guide that X-ray equipment operators use to determine which radiation technique factors to select for each type of radiographic examination.
(64) "Technique factors" means the X-ray system settings selected for a given radiographic examination. They are specified as the peak tube potential in ((kilovolts)) kVp and either:
(a) Tube current measured in ((milliamperes)) mA and exposure time in seconds or pulses; or
(b) The product of tube current and exposure time expressed in ((milliampere seconds)) mAs.
(65) "Tube" means a glass tube that produces an X ray when
high-voltage electricity is passed between the cathode at one end and the anode at the other.

(66) "Tube housing assembly" means the X-ray tube and its housing. It includes high-voltage (and/or) filament transformers and other appropriate elements when they are contained within the tube housing.

(67) "Tube housing port" means the portion of the tube housing assembly that the X rays pass through.

(68) "Useful beam" means the radiation that passes through the tube housing port and the opening of the beam-limiting device.

(69) "Variance" means a department-authorized alternative to a requirement of this chapter.

(70) "X ray" means a beam of ionizing radiation produced by a machine.

(71) "X-ray control" means a device that controls how much electricity enters the X-ray high-voltage generator (and/or) the X-ray tube. It includes equipment that controls the technique factors for an exposure.

(72) "X-ray equipment" means the entire X-ray system or parts of the system.

(73) "X-ray exposure (switch or) button" means the part of the X-ray system that when engaged generates the production of an X ray. (See also "dead-man switch or button.")

(74) "X-ray high-voltage generator" means a device that supplies electrical energy to the X-ray tube to create an X-ray beam.

(75) "X-ray system" means all of the components of a machine used for the controlled production of X rays. It includes minimally an X-ray high-voltage generator, an X-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system, such as the image receptor, are considered integral parts of the system. Types of X-ray systems are:

(a) "Hand-held" means a self-contained X-ray system designed to be held in one or two hands to perform intra-oral radiography. Hand-held X-ray systems used on a tripod or stand are considered to be "portable" systems.

(b) "Mobile" means an X-ray ((equipment)) system mounted on a permanent base with wheels (and/or) casters for moving the X-ray ((equipment)) system fully assembled. It is intended to be taken from one geographical location to another or from one room to another.

(c) "Portable" means an X-ray ((equipment)) system designed to be hand-carried, but not hand-held during use.

(d) "Stationary" means an X-ray ((equipment)) system that is installed in a fixed location, such as bolted to a floor or wall.

(76) "X-ray tube" means any electron tube which is designed to be used primarily for the production of X rays.
WAC 246-225A-020 General requirements and administrative controls. The registrant is responsible for directing the operation of the X-ray system and assuring the provisions of WAC chapter 246-222 WAC (Radiation protection--Worker rights) are met. In addition, the registrant shall:

1. Verify that any operator of the X-ray equipment is trained and able to show that he or she can correctly and safely operate the X-ray equipment used by the registrant. The department may determine compliance by observation, interview, or testing in these subject areas:
   (a) Knowledge of the X-ray system controls and their function;
   (b) Knowledge of radiation safety and shielding methods for both operators and patients;
   (c) Proper image processing.
2. Post a technique chart at each X-ray system's control panel that specifies the following information for the examinations being performed by that system:
   (a) Patient's teeth, jaw, or head anatomy versus technique factors to be used;
   (b) If applicable, settings for automatic exposure devices; and
   (c) The type and size of screen-film combination or other imaging system to be used.
3. Require that all individuals, other than the patient being examined:
   (a) Be positioned so that no part of the body, including the extremities, will be struck by the useful beam;
   (b) Be protected from stray radiation by wearing protective aprons or by being positioned behind protective barriers of not less than 0.25 millimeters lead equivalent; and
   (c) Not be present in the room during the X-ray exposure, except:
      (i) As described in subsection (4)(b) of this section; or
      (ii) When a hand-held, portable, or mobile X-ray system is used.
4. Use mechanical holding devices when a patient, film, or image receptor needs to be supported during an X-ray exposure when the technique permits.
   (a) An individual may not be allowed to routinely hold a patient, film, or image receptor; and
   (b) Holding a patient, film, or image receptor must only be allowed in very unusual and rare situations. In these cases the patient's name, the date, and the name of the person holding the patient must be recorded in writing and maintained by the registrant for at least five years.
5. Comply with the occupational exposure limits and the requirements for the determination of prior occupational dose stated under WAC 246-221-020 (Determination of prior occupational dose) for all individuals associated with the operation of the...
In addition, when protective clothing or devices are worn on portions of the body and a dosimeter is required, at least one dosimeter ((shall)) must be used and documented as follows:

(a) When an apron is worn, the dosimeter ((shall)) must be worn at the collar outside the apron;
(b) The dose to the whole body based on the maximum dose attributed to the most critical organ must be recorded on the reports required under WAC 246-221-230 (Records important to radiation safety). If more than one dosimeter is worn, each dose must be identified with the area where the dosimeter was worn on the body.

(6) Require personnel dosimetry ((monitoring)) of an operator when:
(a) Mobile ((or)) portable, or hand-held X-ray systems are used, i.e., when X-ray exposure buttons or X-ray exposure ((switch)) button cords are used that allow the operator to stand in an unprotected area during exposures; ((or)) and
(b) Measurements by the department show ten percent of the exposure limits as specified under WAC 246-221-010 (Occupational dose limits for adults) are exceeded.

(7) Use only X-ray equipment, and the accessories used in connection with making X rays, that meet the requirements of this chapter.

(8) Not allow anyone in the dental office to operate X-ray equipment for diagnostic purposes when the X-ray equipment:
(a) Does not meet the provisions of this chapter; or
(b) Is malfunctioning or threatens the health or safety of a patient, dental employee, or the public.

(9) Not allow patients to be exposed to the useful X-ray beam except for healing arts purposes. Only a licensed practitioner may authorize an exposure to the useful beam. Deliberate exposure of an individual for the following purposes is prohibited:
(a) Training, demonstration, or other purposes unless there are also healing arts requirements and proper prescription provided; or
(b) Except for exposure required under medicare provisions, any exposure for which the sole purpose is satisfying a third party's prerequisite for reimbursement under any health care plan.

(10) Submit shielding specifications designed by a qualified expert as defined in chapter 246-220 WAC and floor plans to the department for review if the registrant proposes to use ring-detector type CT or medical X-ray systems for dental imaging. The submittal must:
(a) Meet the requirements of WAC 246-225A-050; and
(b) Be based on the criteria and methods found in National Council on Radiation Protection and Measurements (NCRP) report #147, Structural Shielding Design for Medical X-Ray Imaging Facilities, issued November 19, 2004.
((If required by the department, the registrant shall adopt a written X-ray system radiation safety procedure.))

(1) The department may require ((an)) the registrant to adopt a written X-ray system radiation safety procedure if there is reason to believe the registrant needs increased attention because of:
   (a) ((Poor)) Inadequate operator ((staff)) training;  
   (b) Extremely high workload;  
   (c) Increased risk of exposure due to staff supporting patients during radiography;   
   (d) Increased risk of exposure to scattered radiation;  
   (e) Unnecessarily high patient exposure values; or  
   (f) Other similar conditions.

(2) The X-ray system radiation safety procedures ((shall)) must:
   (a) Address patient and occupationally exposed personnel safety; and   
   (b) Define any restrictions of the operating technique required for safe operation of the X-ray system.

WAC 246-225A-050  Dental X-ray facility design.  
((All registrants proposing to use X-ray equipment designed to produce computed tomography images using a "ring detector" type CT, or where medical X-ray systems are used for dental imaging, shall submit shielding and floor plans to the department for review.  The submittal shall be based on the criteria and methods found in National Council on Radiation Protection and Measurements (NCRP) report #147, issued November 19, 2004.  The intent of this requirement is to assure protection of patients, dental employees, and the public.  A copy of this report is available for review at Department of Health, Office of Radiation Protection, 111 Israel Road S.E., Tumwater, Washington.  Shielding and floor plans shall meet the following requirements:))

(1) Each X-ray exposure ((switch or)) button ((shall)) must be located to meet the following criteria:
   (a) For stationary X-ray systems, the X-ray exposure ((switch or)) button ((shall)) must be permanently mounted in a protected area ((such as a corridor outside the room)) so that the operator can make an exposure only from the protected area; and  
   (b) Mobile X-ray systems ((shall)) must have an X-ray exposure ((switch or)) button located at the end of a cord at least twelve feet (3.7 meters) long.
(2) Shielding for cephalometric X ray \((\text{shall})\) must meet the following criteria:
   (a) Be at least one foot (30.5 centimeters) larger, in both the horizontal and vertical directions, than the area of the primary beam where it strikes the nearest wall; and
   (b) Shielding between the nearest wall struck by the primary beam and the next occupied area \((\text{shall})\) must have two-pound lead or equivalent installed in the wall \((\text{based on 20 films per week})\). Exterior walls or concrete block walls need no additional shielding.

(3) Acceptable shielding materials for dental X-ray facilities are as follows:
   (a) The minimum shielding for intra-oral stray radiation protection is standard gypsum wallboard/sheetrock construction (two layers each of five-eighths inch thickness).
   (b) Where windows are provided to observe patients during radiography, the windows are at least one-half inch plate glass, or equivalent ability to reduce exposure.
   (c) All other materials used for shielding between operatories and for operator protection areas are equivalent to 0.2 millimeters of lead.

(4) Barriers \((\text{between})\) surrounding dental X-ray rooms and dental operatories where intra-oral X-ray equipment is installed \((\text{shall})\) must meet the following criteria:
   (a) Be at least six feet (1.83 meters) high and composed of materials capable of reducing scattered radiation as required under subsection (3) of this section;
   (b) There \((\text{shall})\) must be no line of sight between workers or patients in one operatory and the X-ray tube housing assembly in the next operatory when that X-ray tube housing assembly is in its operating position;
   (c) X-ray tube housing assemblies \((\text{shall})\) must not be mounted between operatories on top of barriers less than six feet (1.83 meters) high, unless those barriers are at the foot end of the patient \((\text{couches})\) chairs, and there is no line of sight between adjacent operatories.

**AMENDATORY SECTION** (Amending WSR 08-14-074, filed 6/26/08, effective 7/27/08)

**WAC 246-225A-060 General requirements for all dental X-ray systems.** Registrants shall use only dental X-ray systems and medical X-ray systems for dental imaging that meet the following requirements:

(1) The leakage radiation from the tube housing assembly, measured at a distance of one meter in any direction from the source, \((\text{shall})\) must not exceed 100 milliroentgens in one hour when the X-ray tube is operated at its leakage technique factors.
The department will determine compliance by measuring leakage averaged over an area of 100 square centimeters with no dimension of that area greater than 20 centimeters.

(2) The half-value layer HVL of the useful beam for a given X-ray tube potential must not be less than the values shown in Table 1 of this section. To determine the HVL at an X-ray tube potential which is not listed in Table 1 of this section, linear interpolation or extrapolation may be made.

<table>
<thead>
<tr>
<th>Design operating range</th>
<th>Measured potential</th>
<th>(Half-value layer) HVL</th>
</tr>
</thead>
<tbody>
<tr>
<td>(kVp)</td>
<td>(kVp)</td>
<td>(millimeters of aluminum equivalent)</td>
</tr>
<tr>
<td>70 and below</td>
<td>70 and below</td>
<td>1.5</td>
</tr>
<tr>
<td>Above 70</td>
<td>71</td>
<td>2.1</td>
</tr>
<tr>
<td></td>
<td>80</td>
<td>2.3</td>
</tr>
<tr>
<td></td>
<td>90</td>
<td>2.5</td>
</tr>
<tr>
<td></td>
<td>100</td>
<td>2.7</td>
</tr>
</tbody>
</table>

(3) If two or more X-ray tubes are controlled by one X-ray exposure switch or button, the tube or tubes in operation must be clearly marked before an exposure, on both the X-ray control panel and near or on the selected tube housing assembly.

(4) The tube housing assembly supports of a stationary, portable, or mobile X-ray system must be adjusted so that the tube housing assembly remains stable and does not drift during an exposure unless the tube housing movement during exposure is a designed function of the X-ray system. Except for X-ray systems specifically designed to be hand-held, an X-ray system or tube housing assembly must not be hand-held by anyone during the exposure.

(5) Except for CT X-ray systems that have a scram button, each X-ray control must have a dead-man switch or button.

(6) Technique indicators must be set as follows:
(a) All exposure technique factors must be set on the control panel before the exposure begins, except when automatic exposure controls are used. When automatic exposure controls are used, any preselected settings for each exposure must be indicated.
(b) On equipment having fixed technique factors, the requirement in (a) of this subsection may be met by permanent markings or labels.

(7) Linearity must be measured and met as follows:
(a) The difference between the ratio of milliroentgens (mR) exposure to (milliampere second (mAs(†))) at one (milliampere (†))mA(†) or mAs setting and the ratio of mR exposure to (milliampere second (†))mAs(†) at another (milliampere (†))mA(†) or mAs setting must not exceed 0.1 times the sum of the
ratios. This is written as:

\[ X_1 - X_2 \leq 0.10 (X_1 + X_2) \]

Where \( X_1 \) and \( X_2 \) are the ratios \((\text{mR/mAs})\) for each mA or mAs setting.

(b) The measurement \((\text{shall})\) must be performed at any selection of mA or mAs without regard to focal spot size, provided neither focal spot size is less than 0.45 millimeters.

(8) When four exposures are made at identical operating settings, the difference between the maximum exposure \((E_{\text{max}})\) and the minimum exposure \((E_{\text{min}})\) must be less than or equal to ten percent of the average exposure \((E)\). This is written as:

\[ (E_{\text{max}} - E_{\text{min}}) \leq 0.1E \]

(9) The difference between the kVp indicated on an X-ray system and the measured kVp \((\text{shall})\) must not be greater than ten percent of the indicated kVp.

(10) Timers \((\text{shall})\) must be able to:

(a) Stop the exposure at a preset time interval, a preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor; and

(b) Reset automatically to the initial setting or to zero when the exposure is stopped.

(11) X-ray equipment \((\text{shall})\) must not be \((\text{operated})\) capable of making an exposure when the timer is set to the zero or off position if either position is provided.

(12) Each X-ray control \((\text{shall})\) must have a visual indicator (such as a light) or audible signal so that the operator knows that X rays are being produced or the exposure is occurring or has ended.

(13) Registrants shall not use dental fluoroscopy without electronic amplification.

AMENDATORY SECTION  (Amending WSR 08-14-074, filed 6/26/08, effective 7/27/08)

WAC 246-225A-070  Special requirements for dental extra-oral radiography. Registrants shall use X-ray systems for extra-oral radiography that meet the following requirements for:

(1) Beam limitation.

(a) X-ray equipment designed for only one image receptor size at a fixed \((\text{source-to-image-receptor distance (SID)})\) must be able to limit the size of the beam at the plane of the image receptor to no larger than the image receptor, and to align the center of the X-ray beam with the center of the image receptor to within two percent of the SID. In the case of extra-oral imaging systems where the image receptor can be turned vertically or horizontally, the beam-limiting device must also be able to be
turned so that the dimensions of the beam match the image receptor dimensions at the image receptor plane.

(b) Intra-oral radiography systems used to perform cephalometric projections, including trans-cranial exams, must be equipped with a stable means to:

(i) Set the source-to-skin distance;
(ii) Comply with the beam size dimensions in subsection (1)(a) of this section; and
(iii) Center the beam to the image receptor as required in subsection (1)(a) of this section.

(c) General purpose medical X-ray equipment used to perform cephalometric exams) dental radiography must:

(i) Have stepless adjustment of the dimensions of the X-ray beam so that the width and height of the X-ray beam are independently adjustable. The minimum beam size at an SID of 100 centimeters must be equal to or less than 10 by 10 centimeters.
(ii) Have a means for operators to visually set the width and height of the X-ray beam. The misalignment of the edges of the visually set light field with the respective edges of the X-ray beam along either the length or width of the visually set light field must not be more than two percent of the distance from the source to the center of the visually defined light field when the surface upon which it appears is perpendicular (at a 90 degree angle) to the central axis of the X-ray beam.
(iii) Have a means to indicate on the X-ray equipment when the axis of the X-ray beam is perpendicular to the plane of the image receptor and to align the center of the X-ray beam to the center of the image receptor to within two percent of the SID (five percent for equipment manufactured before August 1974). Dental lateral jaw examinations are excluded from this requirement.
(iv) Have a beam-limiting device that indicates the X-ray beam size in centimeters or inches at the plane of the image receptor to which the beam-limiting device is adjusted.
(v) Have beam size dimension settings that are able to produce X-ray beam dimensions at the plane of the image receptor to within two percent of the SID when the beam axis is perpendicular to the plane of the image receptor.
(vi) Have SID displayed in inches and/or centimeters. An actual beam size at the plane of the image receptor that matches the indicated size to within two percent of the SID.

(2) Source-to-skin distance) SSD and SID.

(a) Dental extra-oral radiography systems must have a durable, securely fastened means to limit the SSD to not less than 23 centimeters. The requirement may be met when the beam-limiting device provides the required limits.
(b) Dental extra-oral radiography systems in which the SID is not fixed (such as an intra-oral system used for cephalometrics) must have a device or reference that will indicate the actual SID to within two percent of the indicated SID.

(3) Viewing device.

Dental extra-oral radiography installations must provide a viewing device (mirror, video camera, or glass window) designed to reduce exposure) so that operators of the X-ray
equipment may observe the patient's head and neck area during the exposure without being exposed to the primary beam or stray radiation.

(4) Scattered radiation suppressing grids. When using scattered radiation suppressing grids, the grids must be:
   (a) Clearly labeled with the SID for which the grids are designed to be used; and
   (b) Used at the proper SID.

(5) X-ray film and screen requirements.
   (a) X-ray film used for extra-oral imaging must be used before the expiration date specified by the manufacturer.
   (b) The spectral sensitivity of the X-ray film used must be matched by the appropriate spectral output of the intensifying screens used in the cassettes as recommended by the film and screen manufacturers.
   (c) Screens must be free of dirt, abrasions, and discoloration that would cause artifacts on the image.

AMENDATORY SECTION (Amending WSR 08-14-074, filed 6/26/08, effective 7/27/08)

WAC 246-225A-080 Special requirements for dental intra-oral radiography. (1) Registrants using an X-ray system designed for use with an intra-oral image receptor shall use equipment that:
   (a) Limits the source-to-skin distance SSD to not less than 18 centimeters;
   (b) Limits the X-ray beam so that the beam diameter at the minimum SSD is no greater than 7 centimeters in diameter;
   (c) Has an open-ended position-indicating device; and
   (d) Has shielding included in the beam-limiting device or position-indicating device equivalent to that required for the diagnostic source assembly under WAC 246-225A-060(1).
   (2) (After January 1, 2010,) Registrants shall not use diagnostic dental X-ray systems with a fixed, nominal kilovolts peak kVp of less than 55.

NEW SECTION

WAC 246-225A-085 Hand-held X-ray system. The following requirements apply to hand-held X-ray systems:
   (1) Registrants using hand-held X-ray systems must provide for security and safe storage while not in use.
   (2) The image receptor used with hand-held dental X-ray systems must either be:
(a) A speed class of intra-oral film designated as "F," "E/F" or faster; or
(b) A digitally acquired image (CR or DR).

(3) The hand-held X-ray system must be equipped with a backscatter shield of not less than 0.25 mm lead equivalent and 15.2 cm (6 inches) in diameter that can be positioned to within 1 cm of the end of the position indicating device. The hand-held X-ray system must always be used with the backscatter shield in place.

(4) Conditions and restrictions using the predicted whole body dose rate (effective dose) to the operator and shallow dose to the fingers:

<table>
<thead>
<tr>
<th>If the predicted whole body dose rate (effective dose) is:</th>
<th>And the shallow dose rate to the fingers is:</th>
<th>The operator:</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;100 mrem/yr</td>
<td>&lt;1 rem/yr</td>
<td>Can operate equipment with no additional requirements</td>
</tr>
<tr>
<td>&gt;100 mrem/yr</td>
<td>&lt;1 rem/yr</td>
<td>Must wear a leaded apron of 0.25 mm lead equivalent</td>
</tr>
<tr>
<td>&gt;100 mrem/yr</td>
<td>&gt;1 rem/yr</td>
<td>● Must wear a leaded apron of 0.25 mm lead equivalent; and ● Must use equipment for special needs patients outside of routine dental office settings only</td>
</tr>
</tbody>
</table>

AMENDATORY SECTION (Amending WSR 08-14-074, filed 6/26/08, effective 7/27/08)

WAC 246-225A-090 X-ray image processing requirements. Standards in this section are designed to assure that optimal X-ray image quality and diagnostic information are produced so that fewer retakes are needed, and associated patient and operator exposure (are minimal) is minimized.

(1) When performing manual film processing((?) (also known as hand tank processing((?) registrants or an operator working under the registrant's direction shall:
(a) Use appropriate chemicals for manual film processing as indicated in chemical and film manufacturer's labels and recommendations.
(b) Mix chemicals in accordance with the chemical manufacturer's recommendations.
(c) Periodically add film developer/fixer replenisher based on the recommendations of the chemical or film manufacturer. Solution may be removed from the tank to permit the addition of an adequate volume of replenisher.
(d) Completely replace all manual processing chemicals at least every two months, or follow the manufacturer's recommendations for periodic chemistry replenishment and
maintenance, whichever is shorter.

(e) Except when quick developer chemistry is used, post and keep for department inspection, the most recent twelve months of a log that shows when each chemistry change was done and by whom (for department inspection).

(f) Process film to achieve the best image quality by either:
   (i) Following the film manufacturer's published temperature and time recommendations for X-ray film development; or
   (ii) Developing film according to the temperature-time chart in (g) of this subsection.

(g) For standard developer solution, follow the X-ray film developing time specified for the appropriate developer solution temperature in Table 1 of this section:

Table 1

<table>
<thead>
<tr>
<th>THERMOMETER READINGS (DEGREES)</th>
<th>MINIMUM DEVELOPING TIMES (MINUTES)</th>
</tr>
</thead>
<tbody>
<tr>
<td>C</td>
<td>F</td>
</tr>
<tr>
<td>27</td>
<td>80</td>
</tr>
<tr>
<td>79</td>
<td>2</td>
</tr>
<tr>
<td>78</td>
<td>2</td>
</tr>
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<td>77</td>
<td>2</td>
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<td>24</td>
<td>76</td>
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<td>75</td>
<td>3</td>
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<tr>
<td>61</td>
<td>8</td>
</tr>
<tr>
<td>16</td>
<td>60</td>
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<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(h) Use X-ray film developing devices that give:
   (i) The actual temperature of the developer solution;
   (ii) The developing time in minutes and seconds; and
   (iii) An audible or visible signal when developing is complete.

(2) When performing automatic film processing, registrants or an operator working under the registrant's direction shall:
   (a) Set up and maintain automatic film processors so that X-ray image density and contrast are optimal;
(b) Follow the film manufacturer's published specifications for time and temperature, and the processor manufacturer's recommendations for type of developer chemistry used. If manufacturer's specifications are not available, the film must be developed using the developer temperatures and immersion times specified in Table 2 of this section:

<table>
<thead>
<tr>
<th>DEVELOPER TEMPERATURE</th>
<th>PROCESSOR DEVELOPER IMMERSION TIME*</th>
</tr>
</thead>
<tbody>
<tr>
<td>°C</td>
<td>°F</td>
</tr>
<tr>
<td>35</td>
<td>95</td>
</tr>
<tr>
<td>34.5</td>
<td>94</td>
</tr>
<tr>
<td>34</td>
<td>93</td>
</tr>
<tr>
<td>33.5</td>
<td>92</td>
</tr>
<tr>
<td>33</td>
<td>91</td>
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<td>32</td>
<td>90</td>
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<td>31.5</td>
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<tr>
<td>31</td>
<td>88</td>
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<tr>
<td>30.5</td>
<td>87</td>
</tr>
<tr>
<td>30</td>
<td>86</td>
</tr>
<tr>
<td>29.5</td>
<td>85</td>
</tr>
</tbody>
</table>

* Immersion time only, no cross-over time included.

(c) Replenish the developer chemistry to create optimal X-ray images by:

(i) Replacing all automatic processor chemicals at least every month, or follow the manufacturer's recommendations for periodic chemistry replenishment and maintenance, whichever is shorter.

(ii) Posting and maintaining a log that shows when each chemistry change was performed and by whom. The most recent twelve months of the log (shall) must be kept for department inspection.

(iii) Verifying that the processor delivers an adequate rate of developer replenishment; and

(iv) Verifying that standby replenishment, flood replenishment, or prefixed film processing (are) done (periodically) as necessary for facilities with a low X-ray workload.

(3) When developing film, registrants or an operator working under the registrant's direction shall:

(a) Set up darkrooms and daylight film loaders so that film being processed, handled, or stored will be exposed only to light passed through a safelight filter. The filter must be of the type specified by the film manufacturer and must not cause excess fog (evidence of light exposure) on X-ray-exposed film. Fog greater than 0.1 optical density is considered unacceptable.

(b) Use bulbs in the darkroom's safelight of fifteen watts or less.

(c) Mount the safelight in the darkroom at least four feet (1.2 meters) above work areas.

(d)) Use daylight loaders in darkened areas or where light is
dimmed so that the fog standard in (a) of this subsection is met.

(4) When processing digital images, registrants or an operator working under the registrant's direction shall:
   (a) Follow the ((computed radiography (CR) and (direct digital radiography (DR) sensor or detector manufacturer's recommendations to achieve adequate diagnostic image quality for the least possible patient exposure.
   (b) Process CR phosphor plates using the longest processing time recommended by the manufacturer of the plate processor.

(5) The department may make X-ray film development and darkroom tests as necessary to determine compliance with this section.

AMENDATORY SECTION  (Amending WSR 08-14-074, filed 6/26/08, effective 7/27/08)

WAC 246-225A-110 ((Image)) Film processing quality assurance.  
((Beginning January 1, 2010,)) Registrants ((making images on film)) found in violation of WAC 246-225A-090 (1)(f) or (2) shall comply with the following quality assurance requirements for ((X-ray image processing)) a minimum of three months:
   (1) Conduct an acceptable quality assurance program that includes weekly tests of ((manual and automatic)) film processing to include:
      (a) Density ((and contrast on)) of test films; and
      (b) Action taken when test film density ((or contrast)) falls below 15 percent of initial reference levels.
   (2) Keep a written or computer log of all periodic quality assurance testing covered in subsection (1) of this section, including the weekly test films((, from the proceeding twelve months for inspection by the department)).