

Significant Legislative Rule Analysis:
Chapter 246-225A WAC, Rules and Regulations – Radiation Safety and
Diagnostic Imaging Quality Standards for Dental Facilities

Section 1. What is the scope of the rule?

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. What are the general goals and specific objectives of the proposed rule's authorizing statute?

RCW 34.05.328(1)(a) requires that the department "clearly state in detail the general goals and specific objectives of the statute that the rule implements."

RCW 70.98.050 and RCW 70.98.080 designate the Department of Health as the state radiation control agency and gives authority to develop rules and regulations relating to control of sources of ionizing radiation. The general goals are to:

- Provide for occupational and public health and safety protection, and
- Protect the people in Washington State from unnecessary exposure and the hazards associated with use of ionizing radiation; specifically that from X-ray sources and isotopes.

The primary objective is to establish radiation safety requirements for patients, dental employees, and the public by:

1. Requiring optimal processing of x-ray images;
2. Reducing unnecessary exposure to patients and operators related to improper or ineffective x-ray imaging processes; and
3. Complying with the policy of ALARA (As Low as Reasonably Achievable) with respect to radiation exposure.

Section 3. What is the justification for the proposed rule package?

RCW 34.05.328(1)(b) requires that the department determine that the rule is needed to achieve the general goals and specific objectives of the statute and analyze alternatives to rulemaking and the consequences of not adopting the rule.

The proposed rule will achieve the authorizing statute's goals and objectives by establishing facility design and operation requirements for the use of sources of ionizing radiation that the approximately 3,100 dental registrants in Washington must comply with. Adopting criteria for the safe use of hand-held x-ray systems ensures the people of this state are protected from the hazards associated with the use of ionizing radiation while increasing access to dental services.

There is no alternative to rulemaking because development and adoption of requirements regulating ionizing radiation and establishing dental x-ray standards in rule is mandated by statute.

Section 4. What are the costs and benefits of each rule included in the rules package? What is the total probable cost and total probable benefit of the rule package?

RCW 34.05.328(1)(d) requires that the department determine that the probable benefits of the rule are greater than its probable costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the statute being implemented.

The proposed rules include changes to 10 individual rules. The table below provides basic information on the rules that the Department of Health has determined are non-significant. The four significant rules are analyzed in the next section.

Non-Significant Rule Identification

WAC Section	Section Title	Section Subject	Reason
246-225A-010	Definitions	Defines terms/language used in rule text	Adding/modifying definitions for clarity without changing its effect
246-225A-020	General requirements and administrative controls	Gives direction for the safe operation of the X-ray system for the protection of patients and operators.	Moving shielding plan criteria from section 050 to section 020 (criteria related to administrative controls)
246-225A-025	X-ray system radiation safety procedure	Defines reasons for and requirements of a written safety procedure.	Clarifies language without changing its effect
246-225A-050	Dental X-ray facility design	Gives specifications for dental facility design criteria	Moving text to WAC (246-225A-020-General Requirements and Administrative Controls); Clarifies language without changing its effect
246-225A-060	General requirements for all dental X-ray systems	Requirements for X-ray systems for dental imaging	Clarifies language without changing its effect (related to hand-held dental x-ray systems)
246-225A-070	Special requirements for dental extra-oral radiography	Requirements of X-ray systems used for extra-oral dental radiography	Clarifies language without changing its effect
246-225A-080	Special requirements for dental intra-oral radiography	Requirements of X-ray systems used for intra-oral dental radiography	Clarifies language without changing its effect.
246-225A-090	X-ray image processing requirements	Requirements for achieving optimal x-ray image quality	Clarifies language without changing its effect.

Significant Rule Analysis

A. WAC 246-225A-085 *Hand-held X-ray systems*

Overview: The proposed rule authorizes the use of, and establishes requirements for, hand-held x-ray systems. Registrants choosing to purchase and use these systems would be required to:

- provide for security and safe storage of the system while not in use (such as a locking case or locking storage cabinet with limited accessibility)
- use faster intra-oral film speed class or digital image receptors (shorter exposure times and higher quality images)
- use systems equipped with a backscatter shield kept in place during use
- follow shielding and safety requirements (use of lead aprons, limited use) if whole body dose rate or shallow dose rate to fingers exceeds specific levels

The restriction of holding the X-ray tube housing or position indicating device on dental X-ray units was included in the transition from Chapter 246-225 WAC to Chapter 246-225A WAC in 2008. The regulation originally came from the 1997 Suggested State Regulations for Radiation Protection (SSR) developed by the Food and Drug Administration (FDA) and the Conference of Radiation Control Program Directors (CRCPD). At that time, hand-held dental X-ray equipment did not exist. It was not until May 2009 that SSRs were changed to include requirements for hand-held dental X-ray equipment use. The proposed rule requirements are consistent with the applicable SSR and many other states.

The original prohibition prevented holding the tube housing and position indicating device. This was because wall-mounted X-ray units did not have sufficient shielding to be hand-held and therefore posed a higher risk of exposure to the operator. The Office of Radiation Protection, X-Ray Program did extensive performance testing of several models of hand-held dental X-ray units. The results of the tests showed that many of the hand-held units are safe for an operator to use because of inherent shielding. (See appendix A).

Most hand-held units are equipped with backscatter shields which provide adequate protection to the operator. Under the proposed rule, all hand-held units will be required to be equipped with backscatter shields in order to provide exposure protection to the operator. Even with the backscatter shields, some machines will be limited in use if the exposure is above certain specified levels to the whole body and fingers of the operator. These levels are specified in a chart included in the proposed rule text.

Cost/Benefit Analysis: Allowing the use of hand-held dental x-ray units benefits the dental profession by giving flexibility in office setup and providing more options for equipment purchase and use. This proposed change also benefits patient populations that otherwise have limited access for health care because dental professionals can provide services outside the dental facility.

The compact size and ease of mobility of the hand-held units allows a registrant to provide dental X-ray services to more patients and to patients such as special needs populations, nursing home

and care facility patients, and shut-ins that might not otherwise have access to this service. This also makes it a health benefit to those patients being served. Registrants choosing to use hand-held dental X-ray units have the potential to increase their business and the number of patients they serve. This could result in increased revenue.

This proposed rule does not burden registrants with any additional cost for those choosing not to purchase hand-held dental X-ray units. It benefits them by giving the option to purchase and use hand-held units which are currently not allowed in the existing rule without a variance. The proposed rule includes specific requirements that would otherwise be individually addressed under a variance request. By including the requirements in rule and eliminating the need for a variance request for those opting to use hand-held units, the minor cost of completing a variance request is also eliminated.

The cost of a new hand-held unit is approximately \$7,400. By comparison, a wall-mounted stationary unit ranges in price from approximately \$1,000 for a used or refurbished unit to \$6,500 for a new unit. Though the cost of the stationary dental X-ray unit can be significantly less expensive, there are other costs associated with their use such as: operatory design, permits and construction of the operatory, electrical installation, and installation of viewing windows or mirrors. Requirements related to these items are not necessary for the use of hand-held dental x-ray units and so the costs can be avoided.

Most registrants have more than one X-ray unit at their facility so the costs would be multiplied by the number of units they have. Of the current 3,271 registrants with dental X-ray equipment, 2,907 have more than one dental X-ray unit (with the majority having 2-4 X-ray units). A hand-held dental X-ray unit could eliminate the need for multiple stationary units because it can easily and quickly be taken from one operatory to another. Having fewer X-ray units would also be a cost saving on registration fees which are partly based on the number of X-ray units a registrant owns. The current registration fee for each dental X-ray unit is \$27.

B. WAC 246-225A-110 *Film processing quality assurance*

Overview: Guidance for adequate film processing quality assurance has been available for many years. The National Council on Radiation Protection and Measurements (NCRP) included recommendations for film processing and quality assurance in their 2003 *NCRP Report No. 145 – Radiation Protection in Dentistry*. The American Dental Association referenced the NCRP report in their association report update and recommendations (JADA, Vol. 137) in September 2006.

The Department first implemented regulations requiring quality assurance film testing in the creation of Chapter 246-225A WAC which was adopted in 2008. The Department included this new section in the rule because at that time approximately 25% of the facilities inspected were cited for inadequate film processing which resulted in poor image quality and quite often unnecessary X-ray retakes.

The current rule text requires all dental registrants making images on film to do a weekly QA test and keep a written or computer log of all tests and test films from the proceeding twelve months.

Based on inspection results since 2008, the requirement was found to be burdensome to those facilities that were already in compliance with adequate film processing requirements.

Cost/Benefit Analysis: The intention of the proposed rule change is to eliminate the burden of film quality assurance testing for facilities in compliance with film processing requirements. This change would be a cost savings to compliant registrants in staff time, film, and processing fluids necessary to perform and record the weekly tests. Only registrants in violation of film processing requirements are required to conduct weekly QA testing. For these facilities, the proposed rule does not create additional burden.

C. WAC 246-225A-070 *Special requirements for dental extra-oral radiography*

Overview: Manufacturers design and produce X-ray film and screens so that the color of light emitted by the screen matches the color sensitivity of the film, producing optimal image quality at the lowest exposure. Manufacturers also specify the conditions under which their products must be used for optimal performance. Department X-ray inspectors occasionally find dental facilities use incorrect film and screen combinations or use expired film. Inspectors also find facilities use cassettes with dirt, abrasions, or discoloration. This results in images that require higher radiation exposure to the patient to achieve diagnostic quality.

Chapter 246-225A WAC currently does not address these issues. Instead inspectors rely on Chapter 246-225 WAC, *X-rays in the Healing Arts*, which states “Procedures and ancillary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.” The proposed rule provides clarity for dental facilities in Chapter 246-225A WAC by requiring registrants to follow manufacturer’s recommendations for film and screen use. It also includes best practices for screen cleaning specified in section 3.4, *Quality Assurance*, of NCRP Report #145, *Radiation Protection in Dentistry*.

Cost/Benefit Analysis: As a matter of practice, facilities replace film and cassettes when instructed to by inspectors. Because this is current practice, the estimated cost of this proposed rule is zero dollars. However, those registrants who do not voluntarily comply would be required to discard expired film, or in the case of mismatched film and screen, order the proper film or new screens for their cassettes. This could result in a cost of \$80 - \$155 per replacement screen or \$125 - \$190 per case of film. If properly maintained, cassettes can last for several years. Existing supplies of mismatched or expired film would need to be discarded and new film ordered. This would be a one-time cost for the replacement film. The department estimates the total cost of this proposed rule ranges from \$0 to \$345.

The benefit of the proposed rule is reduced patient exposure and increased image quality which leads to better patient care.

D. WAC 246-225A-090 *X-ray image processing requirements*

Overview: 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.

Suggested State Regulations for Radiation Protection developed by the FDA and CRCPD in May 2009 is less prescriptive in “how” to achieve clear images and written in an outcome based format. 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 image clarity outcome requirements.

Cost/Benefit Analysis: The benefit of the proposed change allows more flexibility in meeting an outcome based standard for image clarity. There is no additional cost to registrants as a result of this proposed change. Registrants who already comply with adequate fog levels will not be required to make any changes to existing safelight bulbs or placement. Those registrants who do not comply with fog limits will be required to make changes even if the proposed rule is not adopted.

Cost/Benefit Conclusion

The only additional costs that dental facilities would be required to take on as a result of the proposed rule changes are:

1. Replacing dental x-ray film that is expired (beyond the manufacturer’s suggested use date),
2. Replacing x-ray film and/or screen if the combination they are currently using is incompatible, or
3. Replacing x-ray cassette screens that are damaged or discolored and causing artifacts on x-ray film images.

Other costs of proposed changes, such as weekly x-ray processor film QA testing, or replacing safelight bulbs in x-ray darkrooms do not pose any additional burden on facilities than what already exists.

Costs associated with a registrant purchasing a hand-held x-ray system are elective costs and are not a burden to the registrant because they are not required by the proposed rules to purchase and use these systems. We suspect that the use of these systems will become more prevalent as this type of technology advances and older technology becomes obsolete. At this time, hand-held systems are most likely to be used under specific conditions such as:

- oral surgery procedures when patients are under general anesthesia
- dental implant procedures
- for special needs patients with lack of mobility, confinement, or body position make it virtually impossible for use of stationary x-ray units
- emergency situations or accident victims
- geriatric patients or shut-ins outside of the office setting

Based on the preceding cost benefit analysis, the department determines the benefits of improved patient safety and facility flexibility in providing dental services outweigh the minimal costs imposed by the proposed rules.

Section 5. What alternative versions of the rule did we consider? Is the proposed rule the least burdensome approach?

RCW 34.05.328(1)(e) requires that agencies determine, after considering alternative versions of the rule and this analysis, that the rule being adopted is the least burdensome alternative for those required to comply that will achieve the general goals and specific objectives of the statute.

Department of Health staff worked closely with the Washington State Dental Association, stakeholders, and manufacturers of hand-held dental X-ray equipment to minimize the burden of this rule without compromising occupational or public health. For example, we requested input from registrants and stakeholders on proposed rule text impact. Staff worked with manufacturers of hand-held equipment to conduct extensive safety tests of various models of equipment. We also reviewed guidance from the FDA, American Dental Association, and other state's regulations. In the course of these efforts, we assessed and rejected the following alternative versions:

A. Hand-held X-ray equipment use:

Alternative version #1: Leave rule text as is.

Compared to this alternative version, the proposed rule is less burdensome for those required to comply with it. Leaving the rule text as it currently is limits dental registrants' use of hand-held x-ray equipment. A registrant would either not be allowed to use the equipment, or would be required to go through a variance request process.

Alternative version #2: Modify rule text to allow hand-held for unlimited use.

Although this version may be the least burdensome to the registrant, it was rejected because it does not achieve the statutory goals and objectives of providing for occupational and public health and safety, and to protect the people in Washington State from unnecessary exposure and the hazards associated with the use of ionizing radiation. Some hand-held devices do not provide adequate shielding for the operator.

Alternative version #3: Modify rule text to allow hand-held for special populations only and not for routine office use.

Compared to this alternative version, the proposed rule is less burdensome for those required to comply with it because it would be less restrictive on where the registrant can use the equipment. By allowing use of hand-held equipment in a routine office setting the registrant may not need to purchase multiple stationary x-ray units, which could be a significant cost savings. It would also allow for increased workload and potential increased income.

B. Weekly quality assurance testing:

Alternative version #1: Leave rule text as is.

Compared to this alternative version, this proposed rule is less burdensome for those required to comply with it. The proposed rule reduces the number of registrants required to conduct QA testing to only those that do not have adequate film processing. For those required to continue weekly QA testing, there is no change from the existing rule. Registrants with adequate x-ray

film processing would no longer be required to perform weekly processor QA tests. This is a cost savings to the registrant in supplies (i.e. film, developer fluids, records, etc.) and staff time to perform the weekly tests.

Alternative version #2: Modify the rule text to change QA frequency for all registrants.

Although this version may be the least burdensome to the registrant, it was rejected because it does not achieve the statutory goals and objectives of providing for occupational and public health and safety, and to protect the people in Washington State from unnecessary exposure and the hazards associated with the use of ionizing radiation. Weekly QA testing is necessary for those registrants with inadequate film processing to protect patients from unnecessary exposure related to x-ray retakes as a result of poor image quality.

C. Adding film/screen requirements:

Alternative version #1: Leave rule text as is.

Although this version may be the least burdensome to the registrant, it was rejected because it does not achieve the statutory goals and objectives of providing for occupational and public health and safety, and to protect the people in Washington State from unnecessary exposure and the hazards associated with the use of ionizing radiation. Specifying film and screen requirements in Chapter 246-225A WAC to clarify existing performance requirements in Chapter 246-225 WAC protects patients from unnecessary exposure related to x-ray retakes as a result of poor image quality.

D. Modification of safelight requirements:

Alternative #1: Leave rule text as is.

Compared to this alternative version, this proposed rule is less burdensome for those required to comply with it because it is less prescriptive in “how” to set up x-ray darkrooms and is more “outcome based” to achieve less film fogging. Registrants would no longer be required to use a specific wattage of safelight bulb, or to mount the safelight at a specified location in the darkroom. It is a cost savings for the purchase of a new safelight, bulb, or remounting of the safelight.

Least Burdensome Determination

Based on this analysis and the alternatives considered, the Department of Health determined that the rule being adopted is the least burdensome alternative for those required to comply that will achieve the general goals and specific objectives of the statute being implemented.

Section 6. Did we determine that the rule does not require anyone to take an action that violates another federal or state law?

RCW 34.05.328(1)(f) calls for a determination that the rule does not require those to whom it applies to take an action that violates requirements of another federal or state law.

The Department of Health determined that the rule does not require those to whom it applies to take an action that violates requirements of federal or state law.

Section 7. Did we determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless the difference is required in federal or state law?

RCW 34.05.328(1)(g) requires a determination that the rule does not impose more stringent performance requirements on private entities than on public entities unless required by law.

The Department of Health determined that the rule does not impose more stringent performance requirements on private entities than on public entities.

Section 8. Did we determine if the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, did we determine that the difference is justified by an explicit state statute or by substantial evidence that the difference is necessary?

RCW 34.05.328(1)(h) calls for a determination whether or not the rule differs from any federal regulation or statute applicable to the same activity or subject matter.

The Department of Health determined that the rule does not differ from any applicable federal regulation or statute.

Section 9. Did we demonstrate that the rule has been coordinated, to the maximum extent possible, with other federal, state, and local laws applicable to the same activity or subject matter?

RCW 34.05.328(1)(i) requires coordination of the rule, to the maximum extent possible, with other federal, state, and local laws applicable to the same activity or subject matter.

There are no other applicable federal, state, or local laws.