

Preliminary Significant Rule Analysis

WAC 246-290-460 Fluoridation of Drinking Water

January 2016

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Section 1: Describe the proposed rule, including a brief history of the issue, and explain why the proposed rule is needed.

In Washington State, the State Board of Health (board) regulates Group A public water systems (water systems) under Revised Code of Washington (RCW) 43.20.050. Under RCW 70.119A.080, the Washington State Department of Health (department) is directed to administer a Group A drinking water program. Washington Administrative Code (WAC) 246-290-460, Fluoridation of drinking water, sets the allowed fluoridation concentration range for water systems that add fluoride to their water for dental health benefits.

To meet these obligations, both the board and department rely on federal agencies that evaluate best available science to guide rule making and program administration. For standards regarding the safety of drinking water, the board and department rely predominantly on the U.S. Environmental Protection Agency. For setting the optimal fluoride concentration, we rely predominantly on guidance from U.S. Department of Health and Human Services (HHS).

Washington State does not require public water systems to add fluoride to drinking water. The decision to fluoridate community drinking water resides with the community, whether a water district under RCW 57.08.012 or a municipality making a decision under its authority. When a community makes the choice to add fluoride to its drinking water, the department works with them to ensure that the treatment is designed, installed, and operated correctly and meets the fluoride safety standards established by the NSF.

Community water fluoridation (the controlled addition of a fluoride compound to a water system to achieve a concentration optimal for dental caries prevention) is a major factor responsible for the decline in prevalence (occurrence) and severity of dental caries (tooth decay) during the second half of the 20th century¹. On April 27, 2015, the HHS updated its recommendations related to community water fluoridation². For community water systems that add fluoride, HHS now recommends an optimal fluoride concentration of 0.7 milligrams/liter (mg/L). The earlier HHS recommendation for fluoride concentrations was based on the assumption that people in warmer climates consume more water than those in cooler climates, and thus potentially consumed more fluoride. The standard was then calculated based on outdoor air temperature of geographic areas in the United States and ranged from 0.7–1.2 mg/L. A more recent study found that water consumption is consistent across all temperature regions in the United States³. The proposed new single optimal concentration of fluoride in drinking water is the concentration that provides the best balance of protection from dental caries while limiting the risk of dental fluorosis and is supported by the American Dental Association (ADA)⁴ and the World Health Organization⁵.

¹ Centers for Disease Control and Prevention. Achievements in public health, 1900-1999: Fluoridation of drinking water to prevent dental caries. MMWR Morb Mortal Wkly Rep 1999;48 (41):933-40.

² Department of Health and Human Services (US), U.S. Public Health Service Recommendation for Fluoride Concentration in Drinking Water for the Prevention of Dental Caries. Public Health Reports 2015;130:1-14.

³Heller KE, Eklund SA, Burt BA. Dental Caries and dental fluorosis at varying water fluoride concentrations. J Public Health Dent 1997;57(3):136-43.

⁴ Palmer, Craig. "ADA Supports New Government Fluoride Recommendation." ADA News. American Dental Association, 27 Apr. 2015. Web. 23 Dec. 2015.

⁵ http://www.who.int/water_sanitation_health/oralhealth/en/index2.html

The proposed rule:

1. Incorporates the new federal recommendation for water systems that fluoridate to maintain a single optimal fluoride concentration level of 0.7 mg/L.
2. Reduces the operating tolerance allowed in Washington State from 0.8 to 1.3 mg/L, down to 0.5 to 0.9 mg/L.
3. Sets a new requirement for water systems that fluoridate to notify the department before they discontinue fluoridation.
4. Clarifies:
 - a. Daily and monthly monitoring requirements and the method to calculate monthly concentration averages.
 - b. Corrective actions needed when a sample or measurement is out of operating tolerance or off measure.
 - c. The reference to the current “Standard Methods for the Examination of Water and Wastewater” manual (January 2012) for conducting analyses and associated procedures, or other department-approved procedures.

This proposed rule does not apply to naturally occurring fluoride found in drinking water supplies. It only applies to water systems that add fluoride for dental health benefits.

Section 2: Is a Significant Analysis required for this rule?

Yes, as defined in RCW 34.05.328, portions of the proposed rule require a significant analysis. However, the department has determined that no significant analysis is required for the following portions of the rule because the changes clarify rule requirements without changing the effect.

Non-Significant Rule Identification

| Description of Proposed Changes | Rationale for Determination of Non-Significance |
|--|---|
| Clarifies daily and monthly monitoring requirements, and the method to calculate monthly concentration averages. | Changes clarify monitoring procedures and do not change the existing requirements. |
| Clarifies corrective actions when a sample or measurement is out of operating tolerance or off measure and defines these terms. | Changes clarify corrective actions and updates definitions, and do not change the existing requirements. |
| Updates the reference to the current “Standard Methods for the Examination of Water and Wastewater” manual (January 2012), for conducting analyses and associated procedures, or other department-approved procedures. | The change removes the phrase “the most recent version” of the manual and adds the date of the manual’s publication for clarity. The change clarifies the existing requirement without material change. The proposal also adds a phrase to conduct analyses using “other department-approved procedures” which are determined to be equivalent but no more stringent than the procedures in the manual. |

The remaining changes are significant under RCW 34.05.328(5) and are analyzed in section 5 of this analysis.

Section 3: Clearly state in detail the general goals and specific objectives of the statute that the rule implements.

RCW 43.20.050(2)(a) directs the board to:

Adopt rules for Group A public water systems, as defined in RCW 70.119A.020, necessary to assure safe and reliable public drinking water and to protect the public health. Such rules shall establish requirements regarding:

- (i) The design and construction of public water system facilities, including proper sizing of pipes and storage for the number and type of customers;*
- (ii) Drinking water quality standards, monitoring requirements, and laboratory certification requirements;*
- (iii) Public water system management and reporting requirements;*
- (iv) Public water system planning and emergency response requirements;*
- (v) Public water system operation and maintenance requirements;*
- (vi) Water quality, reliability, and management of existing but inadequate public water systems; and*
- (vii) Quality standards for the source or supply, or both source and supply, of water for bottled water plants.*

Additionally, RCW 43.20.050(2)(f) directs the board to:

Adopt rules for the prevention and control of infectious and noninfectious diseases.

The proposed rule implements the general goals and specific objectives of the statutes identified above by establishing operational standards for public water systems that choose to fluoridate, and by establishing a notification requirement for public water systems when they choose to stop fluoridating drinking water.

Section 4: Explain how the department determined that the rule is needed to achieve these general goals and specific objectives. Analyze alternatives to rulemaking and the consequences of not adopting the rule.

The proposed rule meets the general goals and specific objectives identified in RCW 43.20.050 by incorporating the new HHS recommendation to maintain an optimal fluoride concentration of 0.7 mg/L in water systems that choose to fluoridate. If the board takes no action, the current rule will remain in effect and water systems will continue to add fluoride to drinking water at the higher level (0.8 mg/L to 1.3 mg/L). The department assessed the current rule chapter, the authorizing statute, and the new HHS

recommendation and determined that the proposed rule amendments to incorporate the new optimal fluoride level and adjust the operating range downward are needed to achieve the goals and objectives. There are no feasible alternatives to rulemaking.

Section 5: Explain how the department determined that the probable benefits of the rule are greater than the probable costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the statute being implemented.

As identified in Section 1, the proposed rule would revise requirements for water systems that choose to fluoridate. The department determined the proposed revisions include some significant legislative rule changes that are subject to the requirements of RCW 34.05.328(5).

The proposed rule makes the following significant changes:

1. Reduces the operating range from the current range of 0.8 to 1.3 mg/L, down to 0.5 to 0.9 mg/L based on the new HHS recommendation to maintain an optimal concentration of fluoride in drinking water of 0.7 mg/L. This proposed requirement provides the best balance of protection from dental caries while limiting the risk of dental fluorosis; and
2. Requires water systems to notify the department before they discontinue fluoridation.

Proposed change 1: Reduces the operating range from 0.8 to 1.3 mg/L, down to 0.5 to 0.9 mg/L based on the HHS optimal fluoride concentration of 0.7 mg/L

Benefits: The HHS set the new recommended optimal concentration at 0.7 mg/L after considering:

- Scientific evidence related to the effectiveness of water fluoridation in caries prevention and control across all age groups,
- Fluoride in drinking water as one of several available fluoride sources,
- Trends in the prevalence and severity of dental fluorosis, and
- Current evidence on fluid intake of children across various outdoor air temperatures.

The proposed rule lowers the allowed operating range of fluoride concentration from 0.8 to 1.3 mg/L, down to 0.5 to 0.9 mg/L. The low end of the range of 0.5 mg/L ensures the fluoride concentration is sufficient to provide some public health benefit of reducing dental caries while the high end of the range of 0.9 mg/L also provides a public health benefit, but is unlikely to result in moderate to severe dental fluorosis⁶.

⁶ Heller KE, Eklund SA, Burt BA. Dental Caries and dental fluorosis at varying water fluoride concentrations. J Public Health Dent 1997;57(3):136-43.

The department reviewed the HHS analysis and examined other literature on community water fluoridation and concurs with the new HHS recommendation. Documented risks of community water fluoridation are limited to dental fluorosis, a change in dental enamel that is primarily cosmetic in its most common form.

- In the United States today, most dental fluorosis is mild, with no effect on how teeth look or function⁷.
- Moderate to severe dental fluorosis is rare when the concentration of fluoride in drinking water is around 1 mg/L, but begins to become significant at concentrations close to 2 mg/L⁸.

Data from the 1986 – 1987 Oral Health of United States Children survey indicate that dental caries in children gradually decrease as the fluoride concentration in water increases, from negligible concentrations up to concentrations of 0.7 mg/L⁹. This survey is the only national peer-reviewed survey that has assessed dental caries and the child's water source, allowing a linkage of fluoride concentration in the water source to dental health. No data are available to define a dose-response relationship between fluoride intake and caries for adults¹⁰.

The original operating range of 0.8 to 1.3 mg/L was established based on air temperature variability and assumed differences in water consumption; and provided some flexibility to water systems that fluoridate. Adding fluoride is a process that relies on pumps and other mechanical equipment. As with any process that relies on a mechanical process, it is difficult to maintain a constant fluoride concentration at all times. This is due to flow variations based on changes in customer demand, concentration variations in natural background fluoride levels, instrument precision, and control response or lag time. Water systems that currently add fluoride typically maintain concentration levels that range within plus or minus 0.2 mg/l. A recent study examined how closely water systems that fluoridate successfully met their target concentration. It showed that 100% of the water systems were able to meet their target concentration rate 80% of the time. In other words, of the 40 water systems that participated, all had results within plus or minus 0.2 mg/L of their target concentration rate at least 80% of the time. The implication of this study is that some water systems may have to make additional fine adjustments of their fluoride addition processes to consistently achieve results of plus or minus 0.2 mg/L from the target concentration rate of 0.7 mg/L¹¹. Ultimately the effective range of plus or minus 0.2 mg/L around the 0.7 mg/L concentration rate is effective in allowing a reasonable margin of operating tolerance, while protecting the public by having an effective concentration on an average basis, which is appropriate for a long-term benefit¹².

⁷ Department of Health and Human Services (US). U.S. Public Health Service Recommendation for Fluoride Concentration in Drinking Water for the Prevention of Dental Caries. Public Health Reports 2015;130:1-14.

⁸ Pesticide and Environmental Toxicology Section Office of Environmental Health Hazard Assessment, California, Public Health Goal for Fluoride in Drinking Water, December 1997

⁹ Heller KE, Eklund SA, Burt BA. Dental Caries and dental fluorosis at varying water fluoride concentrations. J Public Health Dent 1997;57(3):136-43.

¹⁰ European Food Safety Authority. Scientific Opinion on Dietary Reference Values for fluoride. EFSA Journal 2013;11(8):3332.

¹¹ American Water Works Association, Monitoring Fluoride- How Closely Do Utilities Match Target Versus Actual Levels; Opflow July 2014, 10-14

¹² Pesticide and Environmental Toxicology Section Office of Environmental Health Hazard Assessment, California, Public Health Goal for Fluoride in Drinking Water, December 1997

Costs: In order to estimate costs of this proposed change, the department surveyed the 51 water systems that currently add fluoride to their water. The department received 38 responses on the survey (38/51, 76% response rate)¹³. The costs associated with reducing the operating range based on the HHS optimum fluoridation concentration are included in the table below.

| Component | No cost | Cost increase | Cost savings |
|---|----------------|---|--|
| Lowering the operating range from the existing 0.8 to 1.3 mg/l to the proposed range of 0.5 to 0.9 mg/L ¹⁴ | 24 respondents | 6 respondents (\$70, \$100, \$136, \$400, \$3,000, \$1.3 million ¹⁵) (one-time total cost from each respondent) | 11 (9 respondents) Unspecified cost savings due to slight decrease in fluoride supply costs (2 respondents) (\$146, \$50,000) (one-time total cost savings from each respondent) |

A majority of water systems (35 out of 41, 85%) indicated that they would have no cost or a cost decrease due to changing the operating fluoride concentration range of 0.5 to 0.9 mg/L. A few water systems did indicate that they would have to make adjustments to their standard operating procedures (which had nominal one-time costs ranging from \$70 to \$400). One water system indicated that they would have to make some one-time adjustments and renovations to their fluoride pump equipment to be able to meet the new operating range (estimated cost of \$3,000). Collectively these costs could be viewed as nominal in the comparison of a water system’s annual operating budget.

Proposed change 2: Requires water systems to notify the department before stopping fluoridation

Benefit: The proposed rule will establish a requirement for water systems that currently fluoridate to notify the department before permanently stopping fluoridation. Chapter 290 WAC, Group A public water supplies, requires notification to the department when water systems change treatment practices. The proposed notification requirement is consistent with this policy. Additionally, the department’s division of Prevention and Community Health will have the necessary information to reach out to healthcare providers in the affected areas to inform them that community water fluoridation is no longer in service. This allows providers to inform their patients and parents of young children about other ways

¹³ There were some incomplete responses and several water systems indicated that they would have both anticipated costs and anticipated benefits from the proposed rule. Most of these water systems indicated nominal administrative costs and nominal cost savings (benefit) due to a decrease in fluoride costs.

¹⁴ The department’s survey used a proposed operational range of 0.6 to 1.0 mg/L. The department assumes the costs and benefits provided are comparable and valid for the rule’s proposed operational range of 0.5 to 0.9 mg/L.

¹⁵ One respondent indicated they would incur over \$1.3 million to satisfy requirements in rule. After a follow-up discussion with the water system representative, the representative indicated there would actually be no direct costs attributable to this rule change. There was some concern regarding achieving compliance in the context of a narrower control range. Cost estimates provided are associated with anticipated future upgrading of their system from a constant pumping rate to a variable flow rate system in order to meet energy conservation and water production objectives. The impact of such a change would not be limited to fluoridation, but would impact chlorine disinfection, and any other treatment chemicals currently being fed. Therefore, these costs are not attributable to this proposed rule revision.

to prevent tooth decay such as use of fluoride toothpaste, fluoride drops or tablets, or professionally applied varnish or gel.

Cost: The table below includes results of the survey for this proposed change.

| Component | No cost | Cost increase | Cost savings |
|---|---------|---|--------------|
| Requirement to notify the department when electing to stop fluoridating water | 33 | 5 (\$25, \$68, \$70, \$380, \$500) (one-time total cost from each respondent) | 0 |

The cost of this proposed change will have a nominal impact on water systems. The majority of water systems (33 out of 38, or 87%) responded that the requirement to notify the department would not have an impact. Five water systems provided cost estimates ranging from \$25 and \$500.

Summary of Benefits and Costs

Collectively, the benefit of establishing an effective fluoride concentration range outweighs the costs. The proposed fluoridation range will result in improved dental health and reduced risk of dental fluorosis. Based on input from the water systems, the proposed rule changes will have minimal economic impact on the water systems that elect to fluoridate. Although some water systems did indicate they would need to make minor adjustments to their operating procedures, others indicated they would have a cost savings related to reduced use of fluoride. Based on this analysis, the total probable benefits of the rule exceed the total probable costs.

Section 6: Identify alternative versions of the rule that were considered, and explain how the department determined that the rule being adopted is the least burdensome alternative for those required to comply with it that will achieve the general goals and specific objectives stated previously.

The department considered the following four alternatives to the proposed rule and determined the rule being proposed is the least burdensome alternative for those required to comply that will achieve the general goals and specific objectives of the statute being implemented.

Initially, the department considered an allowed fluoride concentration operating range of 0.6 to 1.0 mg/L. This non-uniform range around the optimal fluoride concentration of 0.7 mg/L was considered mainly because benefits of water fluoridation appear to decrease more significantly below 0.6 mg/L, but also because several water systems informed the department that they normally “targeted” the lower part of the existing operating range of 0.8 to 1.3 mg/L. These water systems indicated that they selected a target in the lower part of the range because of perceived consequences of exceeding the upper limit of

the range. However, during the informal comment period, water systems expressed concern that it would be more difficult to comply with the non-uniform range as compared to a uniform range. Based on this input, the department elected to propose a uniform tolerance range plus or minus 0.2 mg/L around the optimal fluoride concentration. This resulted in the proposed fluoride concentration operating range of 0.5 to 0.9 mg/L. Selecting this uniform range was the least burdensome alternative that will achieve the general goals and specific objectives of the underlying statute.

The following two alternatives were considered in response to comments received during the informal comment period:

- Repeal the rule. The department determined repealing the rule would not be the least burdensome alternative because there would be neither an optimal fluoride concentration nor an operating range established for water systems that choose to fluoridate. Instead the maximum fluoridation additive standard adopted in WAC 246-290-220 would apply. This maximum level is 1.2 mg/L, an amount higher than both the proposed optimal fluoride concentration and operating range. In addition, there would be no sampling or monitoring requirements specifically designed for water systems that choose to fluoridate. These requirements are intended to assist water systems in maintaining the appropriate level of fluoridation for optimal public health benefit.
- Set the optimal fluoride concentration at 0.0 mg/L. This alternative would, in effect, prohibit public water system fluoridation. With a fluoridation concentration of 0.0 mg/L, water systems would not be able to exercise their authority under RCW 57.08.012 which authorizes them to choose water fluoridation. The department determined this alternative did not meet the general goals and specific objectives of the statute being implemented.

The department also considered including only the optimal fluoride concentration of 0.7 mg/L without establishing an operational fluoridation range. However, implementing a singular point at which water systems must operate was not logistically feasible. The existing rule includes an operating range in order to allow water systems to make adjustments based on the normal fluctuations of the water supply. The proposed rule carried the existing framework forward into the proposed rule. In addition, the proposed rule sets the optimal fluoride concentration to provide systems a clear public health goal within the operational range. The department determined adopting only the optimal fluoride concentration would be an overly burdensome alternative for water systems that choose to fluoridate.

Section 7: Determine 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 proposed rule does not require those to whom it applies to take an action that violates requirements of federal or state law.

Section 8: Determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless required to do so by federal or state law.

The proposed rule will not impose more stringent performance requirements on private entities than on public entities. The changes in this rule apply equally to water systems that fluoridate, whether they are publicly or privately owned.

Section 9: Determine if the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, determine that the difference is justified by an explicit state statute or by substantial evidence that the difference is necessary.

The proposed rule does not differ from any applicable federal regulation or statute.

Section 10: Demonstrate that the rule has been coordinated, to the maximum extent practicable with other federal, state, and local laws applicable to the same activity or subject matter.

As described in section 1, the proposed rule has been coordinated to the maximum extent practical with other federal and state laws applicable to the same subject matter.

Appendix A: Water systems that fluoridate

City of Aberdeen
City of Anacortes
City of Bainbridge Island
City of Battle Ground Water Department
Camas Municipal Water Sewer System
Castle Rock Municipal Water
Cathlamet Water Department
Cedar River Water & Sewer District
Centralia Utilities
Chehalis Water Department
City of Cheney
Ellensburg Water Department
City of Everett Public Works Department
Fairchild Air Force Base
City of Fircrest
Forks Municipal Water Department
Highline Water District
Issaquah Water System
JBLM Lewis
JBLM McChord Field
City of Kalama
City of Kelso
Kent Water Department
King County Water District 111
King County Water District No. 90
Longview Water Department

Lynden Water Department
Manchester Water District
City of Montesano
Naval Air Station/Whidbey Island
City of Oak Harbor
Olympic View Water & Sewer District
Pasco Water Department
City of Port Angeles
Port Orchard Water Department
City of Poulsbo
City of Pullman Water Department
Raymond Water Department
City of Redmond Water System
City of Renton
Rockaway Beach Water
Sammamish Plateau Water & Sewer
Seattle Public Utilities
Snohomish PUD 1 - Lake Stevens
South Bend Water Department
Sultan Water Department
City of Tacoma Water Division
Toppenish Water Department
City of Vancouver
West Sound Utility District #1
City of Yakima Water Division