

FLUORIDATION RULES STATEMENT OF NEED AND REASONABLENESS (SONAR)



**Proposed Amendment to Rules Governing Fluoridation of Municipal Water Supplies,
Minnesota Rules 4720.0030, subpart 2.**

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Minnesota Department of Health

Drinking Water Protection Section

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STATEMENT OF NEED AND REASONABLENESS (SONAR) FLUORIDATION

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I. INTRODUCTION

The Minnesota Department of Health (MDH) proposes to update its Public Water Supply Fluoridation Rule (the rule). Recent research shows that MDH can simply lower the fluoride concentration that municipal public water supplies must maintain and still adequately protect public health. Lowering the fluoride concentration will also protect citizens from excessive fluoride and the adverse consequences that excessive fluoride causes. Measured within a range of concentrations, this lowered concentration will also reduce municipal expense.

Municipal public water supplies measure fluoride concentration in two ways: the *average* concentration that municipal water supplies must maintain over time and the *range* that the concentration that municipal water supplies must stay within. MDH proposes to set three new fluoride levels for municipal public water supplies when fluoride is not naturally present:

- an average fluoride concentration of 0.7 milligrams per liter (mg/L);
- a minimum fluoride concentration of 0.5 mg/L; and
- a maximum fluoride concentration of 0.9 mg/L

(Concentrations are expressed in milligrams per liter, which are the same as parts per million.)

Historical background

Community water fluoridation is the controlled addition of fluoride to a community water supply to achieve the optimal fluoride concentration for dental caries prevention. The optimal fluoride concentration is the fluoride concentration that provides the best balance of protection from dental caries, while limiting the risk of dental fluorosis. Fluoridation has contributed greatly to the decline in both occurrence and severity of tooth decay (dental caries), which is one of the greatest public health accomplishments during the second half of the 20th century.

In 1962, studies showed that adding fluoride to public drinking water supplies effectively reduced dental caries. The U.S. Public Health Service (PHS) responded by issuing its national recommendations for optimal fluoride concentrations in drinking water as an effective public health intervention.¹ State and local governments then respond to the national recommendation by deciding whether to fluoridate water supplies.

The state of Minnesota followed the PHS recommendation in 1967, when the Legislature required that both publicly and privately owned municipal water supplies control the fluoride content in community water supplies. The Legislature further required that the state board of health determine and adopt the proper fluoride amounts by rule,² which the state board did in

¹[US National Library of Medicine National Institutes of Health Public Health Reports U.S. Public Health Service Recommendation for Fluoride Concentration in Drinking Water for the Prevention of Dental Caries Report. U.S. Department of Health and Human Services Federal Panel on Community Water Fluoridation, Public Health Reports, July–August 2015, Volume 130, page 1, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4547570/](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4547570/)

² [Minnesota Laws 1967, chapter 603, section 739, https://www.revisor.mn.gov/laws/1967/0/Session+Law/Chapter/603/pdf/](https://www.revisor.mn.gov/laws/1967/0/Session+Law/Chapter/603/pdf/)

1970.³ The 1970 standards required that water supplies maintain an average concentration of 1.2 mg/L; it set the range as neither less than 0.9 mg/L nor more than 1.5 mg/L.

In 1977, the Legislature abolished the state board of health and transferred all its powers and duties to the commissioner of health, who therefore now holds the authority to adopt the rules.⁴ MDH has not revised the 1970 concentrations since.

The PHS reports how much dental caries has decreased. Scientific evidence shows that community water fluoridation has effectively prevented and controlled dental caries across all age groups. Adolescents with dental caries in at least one permanent tooth have decreased from 90 percent among those 12 to 17 years old in the 1960s to 60 percent among those 12 to 19 years old from 1999–2004. Over that time, the number of permanent teeth affected by dental caries declined from 6.2 to 2.6 per person, respectively. Adults also have benefited. The average number of affected teeth decreased from 18 per person among 35 to 44-year-old adults in the 1960s to 10 among 35-to-49-year-old adults from 1999 to 2004.³ One of the main reasons in favor of community water fluoridation is that it prevents dental caries equitably for everyone in the population.⁵

Current state of fluoridation and public health

Currently, oral health practices have changed. People now use the additional fluoride sources that have become available since water fluoridation was first introduced. Two widely used examples are fluoride toothpastes and mouth rinses. This means that fluoride contributed from drinking water, when compared to total fluoride exposure, has changed.⁶ Two recent national studies have shown an increase in rates of dental fluorosis that was very mild or worse since the 1980s.

Dental fluorosis in children aged 8 years and younger has increased from unmonitored, long-term swallowing of fluoride toothpastes and mouth rinses. Children aged 8 and younger are those at risk because permanent teeth are developing then. Most dental fluorosis in the United States is the very mild or mild form, which appears as barely visible white lacy markings or spots on teeth enamel. Children older than 8 years, adolescents, and adults cannot develop dental fluorosis.⁷

Studies conducted in the 1930s showed that the severity of tooth decay was lower and dental fluorosis was higher in areas with more fluoride in the drinking water. In response to these findings, community-water fluoridation programs were developed to add fluoride to drinking water to reach an optimal level for preventing tooth decay, while limiting the chance of developing dental fluorosis.⁸ Reviews of studies conducted after other sources of fluoride were

³ [Minnesota Administrative Rules 4720.0030, subpart 2, which became effective January 1, 1970.](https://www.revisor.mn.gov/rules/4720.0030/)
<https://www.revisor.mn.gov/rules/4720.0030/>

⁴ [Minnesota Laws 1977, chapter 305, section 39.](https://www.revisor.mn.gov/laws/1977/0/Session+Law/Chapter/305/pdf/)
<https://www.revisor.mn.gov/laws/1977/0/Session+Law/Chapter/305/pdf/>

⁵ [Community water fluoridation: Studying the impact of fluoride cessation in Calgary](https://obrieniph.ucalgary.ca/fluoride2016-2)
<https://obrieniph.ucalgary.ca/fluoride2016-2>

⁶ [Community Water Fluoridation https://www.cdc.gov/fluoridation/faqs/dental_fluorosis/index.htm](https://www.cdc.gov/fluoridation/faqs/dental_fluorosis/index.htm)

⁷ [Community Water Fluoridation https://www.cdc.gov/fluoridation/faqs/dental_fluorosis/index.htm](https://www.cdc.gov/fluoridation/faqs/dental_fluorosis/index.htm)

⁸ [Community Water Fluoridation https://www.cdc.gov/fluoridation/faqs/dental_fluorosis/index.htm](https://www.cdc.gov/fluoridation/faqs/dental_fluorosis/index.htm)

introduced, especially fluoride toothpaste, showed beneficial effects from community water fluoridation were still apparent over time.⁹

An extreme overexposure to fluoride leads to severe skeletal fluorosis, a bone disease caused by excessive fluoride intake over a long time. In advanced stages, skeletal fluorosis can cause pain or damage to bones and joints. Fortunately, this is a rare condition in the United States.⁶ To protect against it, the U.S. Environmental Protection Agency (EPA), which sets regulatory standards for drinking water safety, has set the current enforceable maximum fluoride concentration at 4.0 mg/L (or parts per million).⁹

Although tooth decay has notably declined, it remains one of the most common chronic diseases among children ages 6 to 19 years. It can lead to pain, infections, and difficulty eating and sleeping—all of which affect school performance.¹⁰ In 2015, the Minnesota Department of Health Oral Health Program led an open-mouth assessment of caries experience and dental sealants in third grade students in Minnesota public schools.¹¹ In 2015, 17 percent, or nearly 2 out of every 10, Minnesota third graders had untreated tooth decay. The United States median (1998–2015) was 20 percent or 2 out of every 10 third graders.¹²

Thus, we know that fluoridation remains important. MDH needs to update these rules for two reasons: first, to reflect current evidence-based research; and second, to conform the rules to current practice. The 1962 national drinking water standards for community water fluoridation were a range of 0.7–1.2 mg/L, which did not have a corresponding target optimal concentration. In 2011, the Centers for Disease Control (CDC),¹³ through the U.S. Public Health Service (PHS), recommended that the U.S. update and replace these 1962 drinking water standards with a target optimal concentration of 0.7 mg/L; the CDC did not propose a corresponding range with the concentration. In 2015, the CDC made its proposed target optimal concentration of 0.7 mg/L its final recommendation number, again through the PHS.

With this rule revision MDH proposes to set the average fluoride concentration for municipal public water supplies when fluoride is not naturally present to 0.7 milligrams per liter (mg/L). MDH further proposes to regulate this average within a range between a minimum fluoride concentration of 0.5 mg/L and a maximum fluoride concentration of 0.9 mg/L. MDH chose this concentration of 0.7 mg/L as the optimal target because the CDC’s current evidence-based research supports it and thus the CDC recommended it. MDH independently adjusted its range to correspond to the 2015 CDC recommended average fluoride concentration for reasons described below.

Community water supplies underwrite water fluoridation costs. Such costs run from 1 to 3 dollars per million gallons for every 0.1 mg/L fluoride added to raw water.¹⁴ This amounts to up

⁹ U.S. Code of Federal Regulations, 40 C.F.R. § 141.62(b)(1) – Maximum contaminant levels for inorganic contaminants, Fluoride, <https://www.govregs.com/regulations/40/141.62>

¹⁰ National Center for Health Statistics, Prevalence and Severity of Dental Fluorosis in the United States, 199-2004 <https://www.cdc.gov/nchs/products/databriefs/db53.htm>

¹¹ Tooth decay in Minnesota children <https://data.web.health.state.mn.us/tooth-decay>

¹² Tooth decay in Minnesota children <https://data.web.health.state.mn.us/tooth-decay#toothDecayPicto>

¹³ The Centers for Disease Control and Prevention (CDC) is a federal agency under the U.S. Department of Health and Human Services that serves as “the nation’s health department.”

¹⁴ Rindal D, Thoele MJ, Using Analysis of Raw Water Samples to Inform Proposed Adjustment of Fluoride Levels in Minnesota’s Public Water Systems. Poster Number 66, Abstract number 81. National Oral Health Conference, Kansas City, Missouri, April 27, 2015.

to tens of thousands of dollars per year in chemical costs for larger municipalities using source waters that are low in natural fluoride, making cost saving another consideration for revising MDH's fluoridation rules.

Methodology

MDH started calculating the revised target optimal fluoride concentration with the CDC's current evidence-based research in 2017. MDH also pursued improving the balance between maintaining tooth decay prevention and reducing the enamel fluorosis risks associated with higher fluoride exposure.¹⁵

To calculate its proposed range, MDH's fluoridation engineer first reviewed the available peer-reviewed literature.¹⁶ Two studies proved most reliable:

1. US PHS 2015 recommendation, which contained the CDC recommendation; and
2. "Adjusted Fluoride Concentrations and Control Ranges in 34 States: 2006-2010 and 2015", a peer-reviewed article by Barker, Duchon, et al., which validated the CDC recommendation, published in AWWA Journal in 2017.

This review persuaded MDH's fluoridation engineer that an optimal target concentration of 0.7 mg/L based on the 2015 CDC recommendation is reasonable and necessary. Treating the water supplies, however, inevitably causes the fluoride levels to fluctuate. Measuring compliance requires that MDH use a control range around the target concentration. The PHS (now the CDC)¹⁷ last provided control-range recommendations in 1986 that it based on the 1962 PHS recommendations. Those 1986 published levels were 0.1 mg/L below to 0.5 mg/L above an optimal target concentration. The 2015 CDC recommendation did not include such operational control ranges.¹⁸

Updating the calculations

Authority	Target Concentration	Minimum	Maximum	Control Range
Original CDC (1962)	N/A	0.7	1.2	-0.1 to +0.5=0.6 mg/L (1986)
MN Rules / MDH (1970)	1.2	0.9	1.5	0.6 mg/L
CDC (2015)	0.7	None	None	N/A
CDC (2018)	0.7	0.6	1.0	0.4 mg/L
MN Rules / MDH (2019)	0.7	0.5	0.9	-0.2 to +0.2=0.4 mg/L

¹⁵ Per discussion with Merry Jo Thoele, Supervisor, Oral Health Unit, MDH

¹⁶ David Rindal P.E., MDH Fluoride Compliance Engineer

¹⁷ As the PHS became the CDC in June, 1970, this SONAR roughly refers to either of them as interchangeably.

¹⁸ [US National Library of Medicine National Institutes of Health Public Health Reports U.S. Public Health Service Recommendation for Fluoride Concentration in Drinking Water for the Prevention of Dental Caries Report. U.S. Department of Health and Human Services Federal Panel on Community Water Fluoridation, Public Health Reports, July–August 2015, Volume 130, page 1, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4547570/](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4547570/)

The MDH fluoridation engineer based MDH's proposed control range on three sources: previous PHS recommendations; existing Minnesota Rule 4720.0030, which includes a range; and advice from the MDH Oral Health Program.

Reviewing the historical numbers, the MDH fluoridation engineer first noted that the control ranges for both the original CDC and Minnesota Rules 4720.0030 spanned 0.6 mg/L. This means that the variations of allowed levels above and below Minnesota's 1970 target concentration are 0.6 [The CDC's range of +0.5/ to -0.1 equals 0.6 and MR 4720.0030's minimum of 0.9 mg/L to a maximum of 1.5 also equals 0.6.] These ranges are 50% of Minnesota's current target optimal concentration of 1.2 mg/L.

The MDH fluoridation engineer sought to keep the revised range around the new proposed target optimum concentration of 0.7 mg/L consistent with the relative variability of the existing rule. Thus, to maintain a 50% range, he calculated a proposed symmetric control range of +/-25%, or +/-0.2 mg/L. [50% of 0.7 = .35 (or .40 when rounded up) creates a symmetric range of +/- 0.2]

The resulting proposed range then became either 0.2 mg/L more or 0.2 mg/L less than the optimal target concentration and having a control range of approximately 50%, which is consistent with existing Minnesota Rules 4720.0030. Furthermore, as a practical matter, existing drinking-water treatment systems can hold concentrations steady within this range.

The Minnesota Department of Health Oral Health Program supports using the target optimal concentration of less than or equal to 0.7 mg/L to adequately protect against dental caries. Subsequently, research published by Barker, Duchon, et al., corroborated the MDH control range determination of +/-0.2 mg/L.¹⁹ This is the narrowest range that allows all public water supplies, without considering their size or complexity, to comply with the proposed rule, while still allowing existing drinking-water treatment systems the flexibility they need for operations.

Conforming the concentrations to current practice

For its concentrations, MDH proposes, as described in Methodology above, to set the average fluoride concentration for municipal public water supplies, when fluoride is not naturally present, to 0.7 milligrams per liter (mg/L). MDH will regulate this average within a range between a minimum fluoride concentration of 0.5 mg/L and a maximum fluoride concentration of 0.9 mg/L. MDH arrived at these numbers using a combination of federal recommendations and MDH's independent calculations.

In 2011, the CDC, through the PHS, announced its proposed target optimal concentration of 0.7 mg/L as its intended replacement for the 1962 Drinking Water Standards for community water fluoridation, which ranged from 0.7–1.2 mg/L. The PHS did not propose a corresponding range for public water supplies to meet. While waiting for the CDC to release its final recommended target concentration, MDH's fluoridation engineer calculated MDH's range of 0.5 mg/L to 0.9 mg/L as described above in Methodology. MDH, anticipating the CDC announcement of final concentration number would be forthcoming, then publicized both the CDC's proposed target concentration and MDH's calculated range among its approximately 730 municipal public water supplies. The regulated parties too believed the CDC recommendations would soon become the final target concentration and expressed their approval of MDH's proposed new concentrations range by requesting variances under Minnesota law to begin operating immediately within the

lowered numbers. MDH began granting variances on May 21, 2015. In 2015, the CDC made its recommended target optimal concentration of 0.7 mg/L its final standard.

In the meantime, the proposed fluoride concentrations have become current practice. Approximately 550 of 730 regulated municipal water supplies are currently operating under duly granted variances. MDH began rulemaking in 2017 to formally adopt these changes. MDH published its proposed fluoride concentrations in its Request for Comments, which appeared in the *State Register* on July 3, 2017. MDH also notified affected parties of the Request for Comments through multiple means.

Since MDH announced its planned adoption of 0.7 mg/L as its target optimal concentration to be regulated within a range of 0.5 mg/L to 0.9 mg/L, the CDC has proposed its new range of 0.6 mg/L to 1.0 mg/L, as announced in the July 13, 2018 issue of the *Federal Register*.²⁰ MDH's fluoridation engineer considered the CDC's new range and deemed MDH's own calculated ranges to be sufficient to adequately prevent both dental caries and dental fluorosis. Raising the low end of the range would require more supplies to add fluoride to the water and file the requisite reports with MDH. This would increase both municipal supplies' costs and MDH's administrative burden. Raising the upper end would require all 625 fluoridating municipal supplies to add more fluoride. MDH's fluoridation engineer finds no increased benefit that justifies the additional resources that such an incremental change would require from both MDH and the regulated parties. Thus, MDH stands behind its selected optimal concentration of 0.7mg/L within its chosen range of 0.5 to 0.9mg/L.

II. ALTERNATIVE FORMAT REQUEST

Upon request, MDH can make this SONAR available in an alternative format, such as large print, Braille, or cassette tape. To make a request, contact Anita Smith, Drinking Water Protection, Minnesota Department of Health, P.O. Box 64975, St. Paul, Minnesota 55164-0975, Phone: (651) 201-4665, Fax (651) 201-4701 or health.dwp-rules@state.mn.us.

III. STATUTORY AUTHORITY FOR MODIFYING THE RULES

MDH's statutory authority to amend the rules is stated in Minnesota Statutes:

- A. Minnesota Statutes, section 144.12, subdivision 1, states: "The commissioner may adopt reasonable rules pursuant to chapter 14 for the preservation of the public health."
- B. Minnesota Statutes, section 144.45 states: For the purpose of promoting public health through prevention of tooth decay, the person, firm, corporation, or municipality having jurisdiction over a municipal water supply, whether publicly or privately owned or operated, shall control the quantities of fluoride in the water so as to maintain a fluoride content prescribed by the state commissioner of health.

In the manner provided by law, the state commissioner of health shall promulgate rules relating to the fluoridation of public water supplies which shall include, but not be limited to the following:

- (1) The means by which fluoride is controlled;
- (2) The methods of testing the fluoride content; and

²⁰ [Operational Control Range around Optimal Fluoride Concentration in Community Water Systems that Adjust Fluoride, Federal Register, Volume 83, Number 135, pages 32667–32668. The CDC's public comment closed on October 11, 2018, https://www.federalregister.gov/documents/2018/07/13](https://www.federalregister.gov/documents/2018/07/13/Operational-Control-Range-around-Optimal-Fluoride-Concentration-in-Community-Water-Systems-that-Adjust-Fluoride)

(3) The records to be kept relating to fluoridation.”

Under these statutes, MDH has the necessary statutory authority to amend the rules. This rulemaking amends existing rules and thus, Minnesota Statutes, section 14.125, does not apply.

IV. REGULATORY ANALYSIS

Minnesota Statutes, section 14.131, states eight regulatory factors that state agencies must analyze in a SONAR. Paragraphs (A) through (H) that follow address them. Section VI, the Rule-by-Rule Analysis, also addresses some of these factors.

A. Classes of Persons Probably Affected by the Proposed Rule

A description of the classes of persons who probably will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule.

Classes of Persons Affected by the Proposed Rule

The existing rules apply to persons and entities in charge of municipal public water supplies. The proposed revisions to the rule will likely affect:

- Local units of government that own water supplies, which must comply;
- Municipal public water supply customers who consume the water;
- Municipal public water supply owners, which also must comply;
- Drinking-water treatment chemical distributors that supply fluoride additive;
- Drinking-water treatment engineers who must design fluoridation systems;
- Public water supply operators who must oversee fluoridation systems;
- Primary health care providers, e.g. pediatricians; physician assistants; nurse practitioners; who care for children’s health;
- Oral health professionals who seek to prevent or treat dental caries;
- Dental public health organizations who look after population health and policies to pay for it; and
- Dental health professional organizations who service their members’ needs.

Classes of Persons Who Will Bear the Costs of the Proposed Rule

Municipal public water supply owners might have one-time costs to purchase replacement pumps. Fluoridation-pump costs run between several hundred and several thousand dollars. Community water supplies, however, have typically incurred less than \$1,500 in costs, as shown by invoices submitted to MDH for pump-expense reimbursement from Community Fluoridation Equipment grant programs.²¹

Classes of Persons Who Will Benefit from the Proposed Rule

- Minnesota residents: Every person who lives, studies, or works in a municipality in Minnesota will benefit from the proposed rule. Community water fluoridation,

²¹ The 2010/2011 fluoridation equipment grant results show that, \$17,575 of awarded grant funding, with a 20% match requirement, covered 11 pumps (plus other items like tanks and scale). So, even with the match, the average pump cost was less than \$1,500 per system. Rindal D, Community Fluoridation Optimization through a Statewide Competitive Funding Process. Poster Number 12, Abstract number 63. National Oral Health Conference, Milwaukee, Wisconsin, April 30, 2012.

by adjusting the added fluoride to an optimal concentration to prevent tooth decay, continues to effectively reduce tooth decay across populations. The proposed revised fluoride concentrations will adjust fluoride levels to the proper amounts to avoid overexposure and underexposure. Proper fluoride amounts provide the best public health protection possible.

- **Minnesota public water supplies:** Most municipal public water supplies within the state of Minnesota will benefit from the proposed rule. Although fluoride occurs naturally in community drinking water sources throughout Minnesota, at concentrations ranging from non-detectable to 3.8 mg/L, the naturally occurring range is usually lower than the optimal concentration needed to prevent tooth decay. Most Minnesota municipal public water supplies must add fluoride to the water to reach an optimal concentration. The rule proposes a new optimal target concentration that is lower than the existing target concentration of 1.2 mg/L. Lowering the range will prevent unnecessary expense for those now using higher amounts. Some will not have to add fluoride at all. Therefore, most Minnesota municipal public water supplies will reduce the fluoride quantity they add to the water and thus lower their corresponding fluoride chemical supply costs. Current fluoride costs are roughly 2 dollars per million gallons for every additional 0.1 mg/L fluoride added to natural fluoride levels.

B. Probable Costs to Agencies and Effect on State Revenues

The probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

Probable costs to the agency of implementation and enforcement

The probable costs to MDH for implementing the proposed rule amendments will be negligible. Existing agency staff will be able to handle each water fluoridation plant's monthly reports. The Minnesota Public Health Laboratory and existing agency staff will continue to perform comparative analyses on quarterly samples submitted by municipal PWSs. Similarly, MDH staff will continue to receive and evaluate monthly reports submitted by municipal PWSs. Because these monitoring requirements exist under current rule, the agency will only need to replace the existing concentrations with the proposed concentrations to implement the amended rule.

Probable costs to any other agency of implementation and enforcement

MDH is the only agency that has duties under this rule. No other state agency or local public health agencies will incur costs.

Anticipated effect on state revenues

The proposed rule amendments will not affect state revenues.

C. Less Costly or Less Intrusive Methods

A determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

MDH has proposed the least costly and least intrusive methods necessary for achieving the purpose of the rule, namely prescribing the lowest fluoride content in water that still promotes public health by preventing tooth decay.

1. Less costly methods

MDH considered reducing fluoride content to less than 0.5 milligrams per liter for the lower limit. However, when the Public Health Service analyzed data from the 1986–87 Oral Health of United States Children survey, it found that dental caries (tooth decay) gradually declined as fluoride content in water increased from negligible to 0.7 mg/L. Reductions leveled off when concentrations ranged from 0.7 to 1.2 mg/L, making further additions needless. MDH chose 0.5 mg/L as the lower limit to continue preventing dental caries, while allowing water supplies flexibility in their operations.

2. Less intrusive methods

The existing rule and proposed amendments will ensure that water supplies can operate flexibly. Setting the proposed levels of added fluoride at appropriate levels will allow water supplies to maintain a singular target level and be able to measure fluoride levels. Thus, fluoride treatment will be feasible for municipalities that operate under the rules. MDH chose this new proposed range as less intrusive than requiring a narrower operational range, which would require municipal water supplies to control and manage fluoridation treatment more precisely. A narrower range would also need more oversight and a corresponding increase to the agency's regulatory burden, without providing justifiable benefits to public health.

MDH has concluded that no less intrusive methods are available to accomplish the goals of the rules. It asserts that the proposed revisions are necessary and reasonable.

D. Alternative Methods Considered

A description of any alternative methods for achieving the purpose of the proposed rule that were seriously considered by the agency and the reasons why they were rejected in favor of the proposed rule.

As discussed above in Methodology, MDH considered the CDC's new proposed new range of 0.6 mg/L to 1.0 mg/L, which it announced in the July 13, 2018 issue of the *Federal Register*.²² MDH's fluoridation engineer determined MDH's own calculated ranges would be sufficient to adequately prevent both dental caries and dental fluorosis. Raising the low end of the range would require more supplies to add fluoride to the water and file the requisite reports with MDH. This would also increase MDH's administrative burden. Raising the upper end would require all 625 fluoridating municipal supplies to add more fluoride. MDH's fluoridation engineer does not see an increased benefit that justifies the additional resources that such an incremental change would require from both MDH and the regulated parties.

²² [Operational Control Range around Optimal Fluoride Concentration in Community Water Systems that Adjust Fluoride, Federal Register, Volume 83, Number 135, pages 32667–32668. The CDC's public comment closed on October 11, 2018, https://www.federalregister.gov/documents/2018/07/13](https://www.federalregister.gov/documents/2018/07/13/Operational-Control-Range-around-Optimal-Fluoride-Concentration-in-Community-Water-Systems-that-Adjust-Fluoride)

E. Costs of complying with the Proposed Rule

The probable costs of complying with the proposed rule, including the portion of the total costs or consequences borne by identifiable categories of affected parties, such as separate classes of government units, businesses, or individuals.

Any costs of complying with the proposed rule will be borne by municipal public water supply owners or local units of government. MDH expects that affected parties will incur costs because their current methods for adding fluoride and monitoring fluoride level cannot accommodate lower chemical levels. The industry refers to these levels as “feed rates,” which are necessary to achieve the proposed target fluoride content. Therefore, some municipal water supplies may need to make minimal capital improvements by purchasing a new pump. MDH’s fluoridation engineer estimates, based on overseeing the last five years of fluoridation-equipment grants that affected municipal public water supplies would spend approximately \$1,000 apiece for new pumps and pump-related expenses.

F. Probable Cost or Consequences of not adopting the Proposed Rule

The probable costs or consequences of not adopting the proposed rule, including those costs or consequences borne by identifiable categories of affected parties, such as separate classes of government units, businesses, or individuals.

Probable costs of not adopting the proposed rules

Some members of the public could suffer preventable aesthetic and health consequences from not adopting the proposed rule. Some citizens will suffer preventable damage to their teeth from dental fluorosis from added fluoride levels that exceed the lower amount prescribed by the current rule. Affected people could also incur monetary costs from dental treatments to address cosmetic or, in rare cases, health-based conditions from failing to adopt the proposed rule.

Failure to adopt the proposed rule will also cause community water supplies to pay more than they need to from continuing to add excess fluoride to reach the unnecessarily high levels in the current rule. Such costs run from 1 to 3 dollars per million gallons for every 0.1 mg/L fluoride added to raw water. This amounts to up to tens of thousands of dollars per year in chemical costs for larger municipalities using source waters that are low in natural fluoride. The difference in chemical cost from fluoridating to a target of 0.7 mg/L rather than 1.2 mg/L is approximately 8 dollars per million gallons. Therefore, the chemical cost savings to community PWSs may range from negligible to \$200,000 per year.

Portion of costs borne by identifiable categories of affected parties

MDH discussed the parties who would benefit from the rule and how they would benefit under factor A of the regulatory analysis above.

Minnesota public water supplies owners would pay unnecessary expenses from unwarranted chemical use.

G. Difference between the Proposed Rule and Existing Federal Regulations

An assessment of any differences between the proposed rule and existing federal regulations and a specific analysis of the need for and reasonableness of each difference.

SONAR: FLUORIDATION

Fluoridating community drinking water is a state issue. No existing federal regulations require adding fluoride to drinking water. The federal Safe Drinking Water Act (SDWA) includes fluoride as a primary regulated contaminant. Fluoride has a maximum contaminant limit (MCL) of 4.0 mg/L and a secondary MCL (SMCL) of 2.0 mg/L. MDH has the sole delegated authority for SDWA enforcement.

H. Cumulative Effect of the Rule

An assessment of the cumulative effect of the rule with other federal and state regulations related to the specific purpose of the rule.

There are no federal regulations on community drinking water fluoridation. No other existing state regulations regulate water fluoridation so no state regulations conflict with this fluoridation rule.

V. ADDITIONAL STATUTORY REQUIREMENTS

A. Performance-Based Rules

Minnesota law (Minnesota Statutes, sections 14.002 and 14.131) requires that the SONAR describe how MDH, in developing the rules, considered and implemented performance-based standards that emphasize superior achievement in meeting MDH's regulatory objectives and maximum flexibility for the regulated party and MDH in meeting those goals.

MDH staff reviewed the following questions:

1. Are there special situations we should consider in developing the rules?
2. Are there ways to reduce the burdens of the rules?
3. Do you have any other insights on how to improve the rules?

This simple rule change only revises the concentration target optimum concentration and range for community water fluoridation. The range of allowed concentrations recognizes that fluoride levels will fluctuate over time due to treatment process and measured levels will vary accordingly. Municipal water supplies must comply.

B. Additional Notice

Minnesota law (Minnesota Statutes, sections 14.131 and 14.23) requires that the SONAR contain a description of MDH's efforts to provide additional notice to persons who may be affected by the proposed amendments to the rules. The additional notice plan consists of the following steps:

1. Mailing the proposed rules and the notice of hearing to all persons who have registered on MDH's rulemaking mailing list under Minnesota Statutes, section 14.14, subdivision 1a.
2. Posting the proposed rules, the notice of hearing, the SONAR, and a description of the new target optimal concentration on MDH's website at:
[Minnesota Fluoridation Rule Revision website at
http://www.health.state.mn.us/divs/eh/water/com/fluoride/rulemaking/index.html](http://www.health.state.mn.us/divs/eh/water/com/fluoride/rulemaking/index.html).
3. Mailing the proposed rules and the notice of hearing to the 730 regulated municipal water supplies.

4. Providing a copy of the notice of hearing, the SONAR, the fact sheet containing a summary of the substantive amendments, and a Web link to the proposed rules via e-mail through MDH's GovDelivery subscriber service and Workspace, MDH's other subscriber-based secure portal.²³ These 897 recipients are the various individuals, groups, and organizations that have signed for updates about Minnesota's fluoridation laws and this rulemaking.
5. Notifying the Minnesota Legislature per Minnesota Statutes, section 14.116 and Minnesota Statutes, sections 121A.15, subdivision 12(2)(b) and 135A.14, subdivision 7(d). This will include sending the proposed rules, SONAR, notice of hearing, and summary of substantive amendments to the chairs and ranking minority members of the legislative policy and budget committees with jurisdiction over the subject matter.

C. Consultation with Minnesota Management and Budget on Local Government Impact

Minnesota Statutes, section 14.131, requires agencies to consult with Minnesota Management and Budget (MMB) to help evaluate the fiscal impact and benefits of the proposed rules on local governments. MDH delivered a copy of the proposed rules and SONAR to the Executive Budget Officer on April 26, 2019.

MDH does not anticipate local agencies will incur costs because of the proposed rules because their fluoridation systems for water supplies already exist. As described in section IV.E. above, compliance costs will be minimal at most.

D. Cost Determination for Small Business or Small City

As required by Minnesota Statutes, section 14.127, the department has considered whether the cost of complying with the proposed rules in the first year after the rules take effect will exceed \$25,000 for any small business or small city. Besides purchasing a pump, as mentioned above, the only obligation that might affect small businesses or small cities is reporting. The time commitment to do so in these rare cases is negligible. Since MDH or mandated reporters (as discussed in Section IV.E) will bear any other costs, which will be minimal, the department has determined that the rules will not exceed \$25,000 for any small business or small city.

E. Section 14.128 Analysis

Minnesota Statutes, section 14.128 requires agencies to determine whether a local government will have to adopt or amend an ordinance or other regulation to comply with a proposed agency rule and submit this determination for ALJ approval. MDH conducted this analysis and found, since MDH has sole jurisdiction over community water supplies and fluoridation, no local government will have to adopt or amend an ordinance or regulation.

²³ The MDH Workspace is a password-protected portal used by department staff, local health departments, and other emergency preparedness and response partners for planning and response work. MDH used the Workspace when it sent out the Request for Comments to 721 contacts.

F. List of Non-Agency Witnesses

When the rule goes to a public hearing, MDH anticipates having the following non-agency witnesses testify in support of the need for and reasonableness of the proposed amendments to the rules:

1. An oral health expert
2. A drinking water professional

VI. RULE-BY-RULE ANALYSIS

MDH proposes the following amendments to the Fluoridation Rules, Minnesota Rules, chapter 4720.0030, subpart 2. After review, MDH has concluded that the amendments are reasonable and necessary to further the goals of the rules.

PART 4720.0030 FLUORIDATION

4720.0030 Subp. 2. Fluoride Content

MDH proposes to set three fluoride levels for municipal public water supplies when fluoride is not naturally present:

- an average fluoride concentration of 0.7 milligrams per liter (mg/L);
- a minimum fluoride concentration of 0.5 mg/L;
- a maximum fluoride concentration of 0.9 mg/L

An average fluoride concentration of 0.7 mg/L

This addition is reasonable and necessary because a fluoride concentration of 0.7 mg/L in drinking water provides the best balance of protection from dental caries while limiting the risk of dental fluorosis.

A minimum fluoride concentration of 0.5 mg/L

A maximum fluoride concentration of 0.9 mg/L

The minimum and the maximum fluoride concentrations, when read together, create the appropriate control range that is the goal of this amendment. A majority of modern treatment and pumping equipment are more likely achieve control ranges of at least 0.4 mg/L wide (e.g. +/- 0.2 mg/L) than they are control ranges only 0.2 mg/L wide. (Duchon et al. 2017) This addition is reasonable and necessary.

VII. CONCLUSION

Based on the foregoing, the proposed rules are both needed and reasonable.

October 7, 2019



Jan K. Malcolm
Commissioner
Minnesota Department of Health

Attachment A: Methods of Notifying and Persons Notified of Request for Comments

- Mailed the Request for Comments to all persons who had registered to be on MDH's rulemaking mailing list under Minnesota Statutes, section 14.14, subdivision 1a.
- Posted the Request for Comments and a copy of the draft rules on MDH's Minnesota Fluoridation Rule Revision web site at: [Request for Comments: MN Fluoride Rule Revision - EH: Minnesota Department of Health](#)
- Published a summary of the Request for Comments and where people could get further information in publications that reached affected parties.
- Waterline, Fall 2018 quarterly newsletter for water operators, city officials, and others interested in news related to public water supplies in Minnesota. The Waterline includes updates on training sessions along with a registration form for various operator schools as well as feature stories of interest to those in the drinking-water profession.
<http://www.health.state.mn.us/divs/eh/water/com/waterline/fall2018.html#fluoride>

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[US National Library of Medicine National Institutes of Health Public Health Reports U.S. Public Health Service Recommendation for Fluoride Concentration in Drinking Water for the Prevention of Dental Caries Report. U.S. Department of Health and Human Services Federal Panel on Community Water Fluoridation, Public Health Reports, July–August 2015, Volume 130, page 1, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4547570/](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4547570/)

[Minnesota Laws 1967, chapter 603, section 739, https://www.revisor.mn.gov/laws/1967/0/Session+Law/Chapter/603/pdf/](https://www.revisor.mn.gov/laws/1967/0/Session+Law/Chapter/603/pdf/)

[Minnesota Administrative Rules 4720.0030, subpart 2, which became effective January 1, 1970. https://www.revisor.mn.gov/rules/4720.0030/](https://www.revisor.mn.gov/rules/4720.0030/)

[Minnesota Laws 1977, chapter 305, section 39, https://www.revisor.mn.gov/laws/1977/0/Session+Law/Chapter/305/pdf/](https://www.revisor.mn.gov/laws/1977/0/Session+Law/Chapter/305/pdf/)

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[Centers for Disease Control and Prevention National Center for Health Statistics, Survey Results and Products from the National Health and Nutrition Examination Surveys:http://www.cdc.gov/nchs/nhanes/nhanes_products.htm.](http://www.cdc.gov/nchs/nhanes/nhanes_products.htm)

[The Community Guide, Dental Caries \(Cavities\): Community Water Fluoridation. Community Preventive Services Task Force. Preventing dental caries: http://www.thecommunityguide.org/oral/fluoridation.html](http://www.thecommunityguide.org/oral/fluoridation.html)

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[CDC, 1986. Water Fluoridation: A Manual for Engineers and Technicians. US Department of Health and Human Services, Public Health Service, CDC, Atlanta. https://stacks.cdc.gov/view/cdc/13103/.](https://stacks.cdc.gov/view/cdc/13103/)

[Community water fluoridation: Studying the impact of fluoride cessation in Calgary https://obrieniph.ucalgary.ca/fluoride2016-2](https://obrieniph.ucalgary.ca/fluoride2016-2)

[Community Water Fluoridation https://www.cdc.gov/fluoridation/faqs/dental_fluorosis/index.htm](https://www.cdc.gov/fluoridation/faqs/dental_fluorosis/index.htm)

SONAR: FLUORIDATION

[U.S. Code of Federal Regulations, 40 C.F.R. § 141.62\(b\)\(1\) – Maximum contaminant levels for inorganic contaminants, Fluoride, https://www.govregs.com/regulations/40/141.62](https://www.govregs.com/regulations/40/141.62)

[Operational Control Range around Optimal Fluoride Concentration in Community Water Systems that Adjust Fluoride, Federal Register, Volume 83, Number 135, pages 32667–32668. The CDC’s public comment closed on October 11, 2018, https://www.federalregister.gov/documents/2018/07/13](https://www.federalregister.gov/documents/2018/07/13)