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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC-2018-0064]

**Proposed Guidance Regarding Operational Control Range
around Optimal Fluoride Concentration in Community Water
Systems that Adjust Fluoride**

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS).

ACTION: Notice; request for comment.

SUMMARY: The Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) announces in this Federal Register Notice a proposed operational control range around optimal fluoride concentration in community water systems that adjust fluoride, and monthly adherence to that range. The proposal is based on analysis of available data, provided in the Background document. CDC is opening a docket to obtain comment on the existence of evidence-based concerns about the appropriateness of the proposed operational control range and criteria for adherence based on measurement capacity or feasibility of maintaining a target level. The operational control range specifies upper and lower limits of variation around a target concentration of fluoride.

Managers of adjusted water systems at state and local levels need this updated operational control range to ensure the maintenance of consistent monthly averages in fluoride concentration that maximize prevention of tooth decay and minimize the possibility of dental fluorosis. The proposed operational control range is 0.6 mg/L to 1.0 mg/L.

CDC bases this guidance on the following considerations:

(1) Concentration of fluoride in water shown to prevent tooth decay and (2) Ability of water systems to control variation in fluoride concentration.

DATES: Written comments must be received on or before [INSERT DATE 90 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2018-**0064** by any of the following methods:

- Federal eRulemaking Portal:
<http://www.regulations.gov>. Follow the instructions for submitting comments.
- Mail: Division of Oral Health, Centers for Disease Control and Prevention, 4770 Buford Highway, MS S107-8, Atlanta, Georgia, 30341. Attn: Docket Number: CDC-2018-0064.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments

received will be posted without change to <http://regulations.gov>, including any personal information provided. For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Valerie Robison, D.D.S., M.P.H., Ph.D., Dental Officer, Division of Oral Health, Centers for Disease Control and Prevention, 4770 Buford Highway, MS S107-8, Atlanta, GA 30341. E-mail: OPTOL2018@cdc.gov, telephone: (770) 488-6054.

SUPPLEMENTARY INFORMATION:

In 2015, the U.S. Public Health Service (PHS) recommended that community water systems maintain a concentration of 0.7 mg/L to achieve a beneficial fluoride level.¹ This recommendation, which updated and replaced the 1962 Drinking Water Standards related to community water fluoridation, did not include an operational control range associated with the recommended level of 0.7 mg/L.^{1,2}

After the 2015 PHS recommendation was issued, several state water fluoridation and drinking water programs contacted the Centers for Disease Control and Prevention (CDC) to request development of revised operational control range guidance around the 0.7 mg/L target level. As part of the range-setting process, these programs requested that

CDC consider how consistently water treatment systems can stay within an operational control range on a daily basis. A detailed summary of the information CDC considered in developing a proposed operational control range recommendation is available in the Background document found in the Supplement Material tab of the docket.

Recommended Operational Control Range

Since water systems tend to favor an operating strategy that has a lower feed rate, or the rate at which product is added, CDC recommends an asymmetrical operational control range of 0.6 mg/L to 1.0 mg/L in order for public water systems to consistently meet the recommended concentration of 0.7 mg/L.³

The lowest concentration of 0.6 mg/L (-0.1 mg/L below the target level of 0.7 mg/L) will allow public water systems to maintain the oral health benefits of water fluoridation. A lowest concentration of 0.6 mg/L in an operational control range has been in effect since 1962 and water systems have demonstrated experience in meeting it in normal operations.^{2,3}

The highest concentration of 1.0 mg/L (+0.3 mg/L above the target level of 0.7 mg/L) will reduce the possibility of dental fluorosis.^{4,5}

An operational control range of 0.4 mg/L (-0.1 mg/L to +0.3 mg/L) [actual values (0.6 mg/L to 1.0 mg/l)] will provide operational flexibility. This is based on data demonstrating the ability of water systems to stay successfully within a particular operational control range.^{4,6,7} A detailed summary of these findings is available in the Background document.

CDC has received requests for criteria that demonstrate compliance with the operational control range. Published studies have shown that water systems are able to maintain at least 80% of daily measurements during the month within the proposed operational control range.^{6,7} Based on these findings, CDC recommends the following operational criteria; the monthly average fluoride level is maintained within the proposed operational control range, and 80% of daily measurements of fluoride are maintained within the proposed operational control range.

In this docket, we are only concerned with the operational control range for water systems that adjust the fluoride level in the water. This request does not apply to water systems that have natural fluoride levels that exceed this recommended level. Further, the issues of whether or not to adjust fluoride in drinking water, as well as the recommended level to which fluoride should be adjusted,

have previously been addressed in the *Federal Register* and are not part of this request.⁸

Note: Public water systems must continue to comply with Environmental Protection Agency (EPA) requirements for a special notice for exceedance of the secondary standard of 2 mg/L (40 CFR 141.208)

(<https://www.epa.gov/dwregdev/drinking-water-regulations-and-contaminants>).

CDC is seeking public comment on the following:

1. Are there any evidence-based concerns about the appropriateness of the proposed operational control range and criteria for adherence based on measurement capacity or feasibility of maintaining the target level?

References

- 1 U.S. Public Health Service Recommendations for Fluoride Concentration in Drinking Water for the Prevention of Dental Caries. Public Health Reports. 2015 July-Aug;130(4):318-331.
- 2 Department of Health, Education and Welfare (US) Public Health Service drinking water standards, revised 1962. Washington: Public Health Service (US); 1962. PHS Publication No. 956.
- 3 Barker LK, Duchon KK, Lesaja S, et al. Adjusted Fluoride Concentrations in 34 States: 2006-2010 and 2015. Journal AWWA. 2017;109(8):2-17.
- 4 Engineering and Administrative Recommendations for Water Fluoridation, MMWR Sept 29,1995/44(RR-13:1-40). Fluoride Recommendations Work Group. Recommendations for using fluoride to prevent and control dental caries in the United States. MMWR Recomm Rep. 2001;50(RR-14):1-42.

- 5 Heller KE, Eklund SA, Burt BA. Dental caries and dental fluorosis at varying water fluoride concentrations. *J Public Health Dent.* 1997;57:136-43.
- 6 Brown R, McTigue N, Graf K. Monitoring fluoride: how closely do utilities match target versus actual levels? *Opflow,* 40;7:10.
<https://doi.org/10.5991/OPF.2014.40.0042>.
- 7 Teefy S. Managing fluoridation within a stringent regulatory framework. Proc 2013 AWWA Water Quality Technology Conference, Oakland, Calif.

- 8 Public Health Service Recommendation for Fluoride Concentration in Drinking Water for the Prevention of Dental Caries. *Fed Regist.* 2015;80(84):24936-24947.
Available at:
<https://www.federalregister.gov/documents/2015/05/01/2015-10201/public-health-service-recommendation-for-fluoride-concentration-in-drinking-water-for-prevention-of>. Accessed 5/11/2018.

Date: July 9, 2018

Sandra Cashman,
Executive Secretary,
Centers for Disease Control and Prevention.

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