

received to both notices, as well as new literature, we revised the previous draft profile (including a revised Minimal Risk Level (MRL)); therefore, on June 21, 2018, ATSDR released a revised draft profile for public comment (83 FR 28849). Because the substantive revisions were limited to the MRLs Appendix, and given the public health demand for the updated toxicological profile, we opted for a 30 day comment period. ATSDR has received requests to extend the comment period for this profile. Accordingly, ATSDR is extending the comment period an additional 30 days. Comments must be submitted by August 20, 2018.

#### Availability

The Draft Toxicological Profiles are available online at <http://www.atsdr.cdc.gov/ToxProfiles> and at [www.regulations.gov](http://www.regulations.gov), Docket No. ATSDR-2015-0004.

#### Pamela I. Protzel Berman,

Director, Office of Policy, Partnerships and Planning, Agency for Toxic Substances and Disease Registry.

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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 October 11, 2018.

**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://www.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. Email: [OPTOL2018@cdc.gov](mailto: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.<sup>1</sup> 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.<sup>1 2</sup>

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.<sup>3</sup>

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.<sup>2 3</sup>

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.<sup>4 5</sup>

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.<sup>4 6 7</sup> 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.<sup>6 7</sup> 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.<sup>8</sup>

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.

Dated: July 9, 2018.

**Sandra Cashman,**

*Executive Secretary, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[Document Identifiers: CMS–10531, CMS–R–43, CMS–10102, CMS–10143, CMS–10261, CMS–10500, and CMS–8551]**

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services, HHS.

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments on the collection(s) of information must be received by the OMB desk officer by August 13, 2018.

**ADDRESSES:** When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions:

OMB, Office of Information and Regulatory Affairs

Attention: CMS Desk Officer

Fax Number: (202) 395–5806 OR

Email: [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov)

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov).

3. Call the Reports Clearance Office at (410) 786–1326.

**FOR FURTHER INFORMATION CONTACT:** Reports Clearance Office at (410) 786–1326.

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term “collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Transcatheter Mitral Valve Repair (TMVR) National Coverage Decision (NCD); Use: The data collection is required by the Centers for Medicare and Medicaid Services (CMS) National Coverage Determination (NCD) entitled, “Transcatheter Mitral Valve Repair (TMVR)”. The TMVR device is only covered when specific conditions are met including that the heart team and hospital are submitting data in a prospective, national, audited registry. The data includes patient, practitioner and facility level variables that predict outcomes such as all-cause mortality and quality of life. In order to remove the data collection requirement under this coverage with evidence development (CED) NCD or make any other changes to the existing policy, we