Small Business Economic Impact Statement

Chapter 246-390 WAC

Drinking Water Laboratory Certification and Data Reporting Rule

Prepared by the Department of Health
on behalf of the State Board of Health

August 3, 2021

SECTION 1:

Describe the proposed rule, including: a brief history of the issue; an explanation of why the proposed rule is needed; and a brief description of the probable compliance requirements and the kinds of professional services that a small business is likely to need in order to comply with the proposed rule.

Background

More than 6.2 million Washington residents get their drinking water from Group A public water systems (Group A water systems). In Washington State, the State Board of Health (board) regulates Group A water systems under Revised Code of Washington (RCW) 43.20.050.

Under RCW 70A.125.080, the Washington State Department of Health (department) is directed to administer a Group A drinking water program with at least the elements necessary to assume primary enforcement responsibility of the federal Safe Drinking Water Act.

The department administers the Group A drinking water program and regulates Group A water systems with a formal agreement with the U.S. Environmental Protection Agency (EPA) known as "primacy". Part of the primacy agreement, under 40 Code of Federal Regulations (CFR) 142.10(b)(3)(i), requires the department to maintain a state program for the certification of laboratories (labs) that conduct analytical measurements of drinking water for federally regulated public water systems

The department's other authorities to regulate Group A water systems come from state laws, like those mentioned above, and Washington Administrative Code (WAC), like the Group A public water supplies rule (Group A rule), chapter 246-290 WAC and chapter 246-390 WAC (Lab rule), which the board is proposing to amend at this time. The department and the board work closely on rulemaking projects, with the department providing expertise, resources, and recommendations to the board. Ultimately, it is the board that has the authority to adopt the proposed changes in this rule.

The board accepted a petition from ToxicFree Future and nine other organizations on October 11, 2017, to set drinking water standards for per- and polyfluoroalkyl substances (PFAS) in chapter 246-290 WAC. The board is revising both the Group A rule and the Lab rule to address these regulatory issues and needs.

PFAS are chemicals that have been used in industry and consumer products such as carpeting, apparels, upholstery, food paper wrappings, fire-fighting foams, and metal plating worldwide since the 1950s. Wide use combined with their persistent and bioaccumulative properties have led to widespread detection of perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), perfluorohexane sulfonic acid (PFHxS), and perfluorononanoic acid (PFNA) in the blood serum of the general U.S. population [1]. Average serum levels of PFAS may be more than 100 times higher than national norms in communities exposed via contaminated drinking water[2]. A recent Center for Disease Control (CDC)/ Agency for Toxic Substances and Disease Registry (ATSDR) study in the community of Airway Heights, Washington showed that study participants had mean serum levels of PFHxS that were 60 times higher than national norms even two years after PFAS contamination had been fully mitigated in their community drinking

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[1] CDC - NHANES, Fourth Report on Human Exposure to Environmental Chemicals, Updated Tables, (January 2019), C.f.D.C.a. Prevention, Editor. 2019, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention: Atlanta, GA.

[2] Frisbee, S.J., et al., *Perfluorooctanoic acid, perfluorooctanesulfonate, and serum lipids in children and adolescents: results from the C8 Health Project.* Arch Pediatr Adolesc Med, 2010. **164**(9): p. 860-9; Li, Y., et al., *Half-lives of PFOS, PFHxS and PFOA after end of exposure to contaminated drinking water.* Occup Environ Med, 2018. **75**(1): p. 46-51; Pitter, G., et al., *Serum Levels of Perfluoroalkyl Substances (PFAS) in Adolescents and Young Adults Exposed to Contaminated Drinking Water in the Veneto Region, Italy: A Cross-Sectional Study Based on a Health Surveillance Program.* Environ Health Perspect, 2020. **128**(2): doi.org/10.1289/EHP5337.

water[3]. Mean serum levels of PFOS and PFOA in participant's serum were 10 and six times higher than national norms, respectively.

Health concerns about PFAS stem from the wide range of adverse effects observed in animal testing. Effects of the best studied PFAS include liver, kidney, thyroid and immune toxicity; developmental and reproductive toxicity, hormone disruption and tumors in certain organs like the liver[4]. The specific profile of effects and the weight of evidence varies by the PFAS examined.

Health researchers are still learning about how environmental exposure to PFAS might affect people's health. The strongest evidence from epidemiology indicates that some PFAS may increase serum cholesterol levels[5], alter liver enzyme levels[6], slightly lower birth weights[7], and reduce immune response to childhood vaccines[8]. Outcomes with more limited evidence of an association with PFAS exposure include thyroid disease, hypertension disorders during pregnancy, reproductive problems, altered hormone levels, and metabolic issues[9].

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[3] CDC/ATSDR PFAS Exposure Assessment Community Level Results for Spokane County (WA) near Fairchild Air Force Base, 2020 https://www.atsdr.cdc.gov/pfas/communities/factsheet/Spokane-County-Community-Level-Results-Factsheet.html

[4] Agency for Toxic Substances and Disease Registry (ATSDR), Toxicological Profile for Perfluoroalkyls - Draft for Public Comment. 2018, U.S. Department of Health and Human Services: Atlanta. p. 852; EPA, *Drinking Water Health Advisory for Perfluorooctanoic Acid (PFOA)*. 2016, Environmental Protection Agency: Washington, D.C. p. 103; EPA, *Drinking Water Health Advisory of Perfluoroctane Sulfonate (PFOS)*, O.o. Water, Editor. 2016, Environmental Protection Agency; EPA, *Human Health Toxicity Values for Perfluorobutane Sulfonic Acid (CASRN 375-73-5) and Related Compound Potassium Perfluorobutane Sulfonate (CASRN 29420-49-3): Public Comment Draft*. 2018; National Toxicology Program (NTP), NTP Technical Report on the Toxicity Studies of Perfluoroalkyl Sulfonates (Perfluorobutane Sulfonic Acid, Perfluorohexane Sulfonate Potassium Salt, and Perfluorooctane Sulfonic Acid) Administered by Gavage to Sprague Dawley Rats P.H. Service, Editor. 2019, U.S. Department of Health and Human Services: Research Triangle Park, NC; National Toxicology Program (NTP), NTP Technical Report on the Toxicity Studies of Perfluoroalkyl Carboxylates (Perfluorohexanoic Acid, Perfluorooctanoic Acid, Perfluorononanoic Acid, and Perfluorodecanoic Acid) Administered by Gavage to Sprague Dawley Rats P.H. Service, Editor. 2019, U.S. Department of Health and Human Services: Research Triangle park, NC; NJDWQI, Health-based Maximum Contaminant Level Support Document: Perfluorononanoic acid (PFNA) 2015, New Jersey Drinking Water Quality Institute Health Effects Subcommittee.

[5] Frisbee, S.J., et al., Perfluorooctanoic acid, perfluorooctanesulfonate, and serum lipids in children and adolescents: results from the C8 Health Project. Arch Pediatr Adolesc Med, 2010. 164(9): p. 860-9; Graber, J.M., et al., Per and polyfluoroalkyl substances (PFAS) blood levels after contamination of a community water supply and comparison with 2013-2014 NHANES. J Expo Sci Environ Epidemiol, 2019. 29(2): p. 172-182; Li, Y., et al., Associations between perfluoroalkyl substances and serum lipids in a Swedish adult population with contaminated drinking water. Environ Health, 2020. 19(1): p. 33.

[6] Bassler, J., et al., *Environmental perfluoroalkyl acid exposures are associated with liver disease characterized by apoptosis and altered serum adipocytokines.* Environ Pollut, 2019. **247**: p. 1055-1063; Salihovic, S., et al., *Changes in markers of liver function in relation to changes in perfluoroalkyl substances - A longitudinal study.* Environ Int, 2018. **117**: p. 196-203; Salihovic, S., et al., *Changes in markers of liver function in relation to changes in perfluoroalkyl substances - A longitudinal study.* Environ Int, 2018. **117**: p. 196-203; Gallo, V., et al., Serum perfluorooctanoate (PFOA) and perfluorooctane sulfonate (PFOS) concentrations and liver function biomarkers in a population with elevated PFOA exposure. Environ Health Perspect, 2012. 120(5): p. 655-60.

[7] Johnson, P.I., et al., The Navigation Guide - evidence-based medicine meets environmental health: systematic review of human evidence for PFOA effects on fetal growth. Environ Health Perspect, 2014. 122(10): p. 1028-39; Meng, Q., et al., Prenatal Exposure to Perfluoroalkyl Substances and Birth Outcomes; An Updated Analysis from the Danish National Birth Cohort. Int J Environ Res Public Health, 2018. 15(9); Wikstrom, S., et al., Maternal serum levels of perfluoroalkyl substances in early pregnancy and offspring birth weight. Pediatr Res, 2019.

[8] National Toxicology Program (NTP), Systematic Review of Immunotoxicity Associated with Exposure to Perfluorooctanoic acid (PFOA) or Perfluoroctane Sulfonate (PFOS). 2016, National Toxicology Program, U.S. Department of Health and Human Services; DeWitt, J.C., S.J. Blossom, and L.A. Schaider, Exposure to per-fluoroalkyl and polyfluoroalkyl substances leads to immunotoxicity: epidemiological and toxicological evidence. J Expo Sci Environ Epidemiol, 2019. 29(2): p. 148-156; Grandjean, P., et al., Serum Vaccine Antibody Concentrations in Adolescents Exposed to Perfluorinated Compounds. Environ Health Perspect, 2017. 125(7): p. 077018; Abraham, K., et al., Internal exposure to perfluoroalkyl substances (PFASs) and biological markers in 101 healthy 1-year-old children: associations between levels of perfluorooctanoic acid (PFOA) and vaccine response. Arch Toxicol, 2020; Timmermann, C.A.G., et al., Serum Perfluoroalkyl Substances, Vaccine Responses, and Morbidity in a Cohort of Guinea-Bissau Children. 2020. 128(8): p. 087002.

[9] Fenton, S.E., et al., Per- and Polyfluoroalkyl Substance Toxicity and Human Health Review: Current State of Knowledge and Strategies for Informing Future Research. Environ Toxicol Chem, 2021. 40(3): p. 606-630; C8 Science Panel. *C8 Probable Link Reports*. 2012 11/28/2013; Available from: http://www.c8sciencepanel.org/prob_link.html.

There is some evidence from occupational and non-occupational studies that PFOA may increase rates of kidney and testicular cancer[10]. Little data are available for other PFAS.

Starting in 2002, PFAS have been detected in U.S. drinking water, primarily near manufacturing facilities, local fire departments, military bases and airports. Between 2013 and 2015, EPA required a representative number of Group A water systems to measure for six PFAS as part of the third Unregulated Contaminant Monitoring Rule (UCMR3)[11].

In Washington State, this UCMR3 sampling included 132 water systems representing 94 percent of people served by Group A water systems. Additionally, voluntary testing by the Navy, Air Force, and Army has discovered additional drinking water contamination in private and public wells on or around four military bases between 2016 and 2020. Proactive testing by nearby public water systems has discovered additional wells that are impacted.

PFAS have been identified in drinking water in Issaquah and in private wells and public water systems at or near four military bases: Naval Air Station (NAS) Whidbey Island, Fairchild Air Force Base, Joint Base Lewis-McChord, and Navy Base Kitsap-Bangor. In each area, the sum of PFOA and PFOS in at least one drinking water well exceeded the lifetime health advisory level (HAL) of 70 parts per trillion (ppt) set by the EPA in May 2016. PFAS-based firefighting foam is the suspected source of contamination at all of these areas. Ongoing investigations may identify other contributing sources.

In Washington, while we know PFAS have been identified in multiple areas, we do not yet know the full extent of PFAS contamination in our drinking water supplies, and the science around PFAS is evolving quickly. In light of this, several Group A water systems have either installed treatment to reduce PFAS or are pursuing treatment.

The board and the department considered setting a state Maximum Contaminant Level (MCL) but ultimately the board directed the department to develop a "state advisory level", which is undergoing a concurrent name change in this proposal to “state action level” (SAL).

The board is proposing amendments to the Lab rule to align laboratory data reporting requirements with the anticipated changes to the Group A rule as related to PFAS. The Lab rule proposal includes a new PFAS template for the purposes of data reporting, adds a requirement for notification when PFAS sample results exceed a SAL, and adds state detection reporting limits (SDRLs) for PFAS. The rule revision also includes technical and clarifying corrections as needed.

Why are the changes to the rule needed?

PFAS contaminant results have never been reported directly to the department or public water system and therefore have never been a required component of the Lab rule. The proposed changes to the Group A rule require corresponding changes to the Lab rule for explicit PFAS reporting requirements and add notification requirements for specific PFAS contaminants. The rule revision also includes technical and clarifying corrections as needed.

The proposed rulemaking will:

- Add the following:

[10] IARC, Some Chemicals Used as Solvents and in Polymer Manufacture, in IARC Monographs on the Identification of Carcinogenic Hazards to Humans. Volume 110. 2017, International Agency for Research on Cancer (IARC): Lyon, France; Shearer, J.J., et al., *Serum concentrations of per- and polyfluoroalkyl substances and risk of renal cell carcinoma.* J Natl Cancer Inst, 2020.

[11] EPAs UCMR3 Webpage: https://www.epa.gov/dwucmr/third-unregulated-contaminant-monitoring-rule

- A new template for reporting PFAS to the department in a revised guidance document: *Laboratory Reporting Guidance*, Publication DOH 331-530, December 2021;
    - A new electronic reporting format in a revised guidance document: *Electronic Reporting Guidance*, Publication 331-289, December 2021;
    - PFAS specific notification requirements;
    - PFAS specific SDRLs; and
    - PFAS specific required analytes.
- Make minor technical changes and clarifying corrections to existing rule language:
    - Clarifies requirements for a lab to report to a public water system when it contracts a sample out to another lab;
    - Requires the contracting lab must notate on the final report to the public water system which sample results were contracted out to another lab;
    - Changes the chronic contaminant reporting timeline from 45 business days to 30 calendar days; and
    - Lowers the SDRL for chloride from 20 milligrams per liter (mg/L) to 2 mg/L and sulfate from 50 mg/L to 2 mg/L.

SECTION 2:

Identify which businesses are required to comply with the proposed rule using the North American Industry Classification System (NAICS) codes and what the minor cost thresholds are.

This industry comprises establishments primarily engaged in performing physical, chemical, and other analytical testing services, such as acoustics or vibration testing, assaying, biological testing (except medical and veterinary), calibration testing, electrical and electronic testing, geotechnical testing, mechanical testing, nondestructive testing, or thermal testing. The testing may occur in a laboratory or on-site. There are 134 labs certified by Washington State Ecology's Laboratory Accreditation Unit (LAU) that can analyze drinking water that originated from Washington state. Out of the 134 labs certified, only 79 labs are located in the state of Washington. Of the 134 labs, 16 certified labs can analyze Washington state drinking water samples for PFAS. There are currently no labs certified to test for PFAS located in the state.

SBEIS Table A:*

NAICS Code (4, 5 or 6 digit)	NAICS Business Description	# of businesses in WA	Minor Cost Threshold = 1% of Average Annual Payroll	Minor Cost Threshold = .3% of Average Annual Receipts
541380	Testing Laboratories	197	$10606	$7878

**Economic Census. Summary Statistics fir the US., States, and Selected Geographies: 2017. Table ID EC1700BASIC.Year: 2017.Dataset: ECNBASIC2017*

SECTION 3:

Analyze the probable cost of compliance. Identify the probable costs to comply with the proposed rule, including cost of equipment, supplies, labor, professional services and increased administrative costs; and whether compliance with the proposed rule will cause businesses to lose sales or revenue.

To gauge the potential impact of the proposed rule the department surveyed all 134 labs to understand new costs to implement the proposed rule. The costs that are presented are estimates for one-time costs and annual costs. One-time costs are costs that a lab would incur only once to comply with the rule, such as paying a print shop to format the new lab report forms. Annual costs are costs that a lab will incur every year, such as the costs associated with annual renewal fees for certification requirements.

The department conducted follow-up interviews with labs when the responses were either incomplete or when the department needed to ask clarifying questions. In some cases, the respondents elected to revise their original responses for accuracy.

The department received 14 responses (10.4 percent) to the survey. The demographic of the respondents are as follows:

- Eight small businesses (50 or less employees) responded:
    - Two are currently certified to run PFAS analysis.
    - Of the remining six small businesses that submitted cost survey results
        - Three are small microbiology and nitrate labs and would not voluntarily add PFAS to their scope of certification and could only incur costs with the technical updates that the department proposed.
        - Two are businesses that could voluntarily add PFAS to their scope of certification but have expressed that they will not do so at this time.

- Six large businesses (over 50 employees) responded:
    - Four are currently certified to run PFAS analysis.
    - Two are businesses that could voluntarily add PFAS to their scope of certification but have expressed that they will not do so at this time.

For the purposes of this analysis certification of new labs to test for PFAS was excluded because on average, a lab can analyze 40 samples for PFAS contaminants per week. Using this average, the 16 labs that are currently certified to run PFAS samples could run 640 samples per week or 33,280 samples per year. As previously reported, the department estimated that approximately 4,000 initial samples taken over the proposed three-year monitoring cycle (2023 – 2025) and therefore the department believes that no additional labs would need to gain certification to meet the State's demand for PFAS analysis.

The new costs to labs for the proposed addition of PFAS SAL exceedance and reporting requirements under WAC 246-390-065 and 246-390-075(17) respectively were also excluded from this analysis. These costs were excluded because none of the labs currently certified to test for PFAS are physically in the state of Washington.

New costs included in this analysis are costs for labs to comply with proposed technical changes to the rule (SBEIS Table 1).

SBEIS Table 1. New costs reported from labs to adhere to rule technical corrections (respondents=14)

Type of Cost	Proposed Rule Section Change	# of Respondents	Cost or Average Cost*	Range*	Cost Description
Annual cost					
Labor	246-390-055 (1)(b)	1	$500	n/a	To notify customers
Labor	246-390-055 (1)(e)	1	$500	n/a	To notate on customer reports

One-time cost

Labor	246-390-075 (6)	1	$50	n/a	To update internal documents and programs
Labor	246-390-075 Table 4	7	$150	$0 - $1000	To update templates

*These costs should not be summed and should be analyzed as individual rows

SECTION 4:
Analyze whether the proposed rule may impose more than minor costs on businesses in the industry.

When considering the minor cost threshold of business in this industry, only the costs of the rule to adhere to technical corrections should be considered, as none of the labs that are currently certified to test for PFAS are physically located in the State of Washington.

Of the 14 labs that responded to the cost survey 7/14 reported they would have new costs associated with technical corrections. Based on data collected in the cost survey the department finds that there will be one-time costs as well as annual costs:

- One-time costs ranged from $0 - $1,000 and were associated with labor costs to update internal documentation and programs. These one-time costs should not be summed and should be considered individually as they may not all apply to each lab.

- Annual costs reported were $500 associated with notification of customers and $500 associated with notating on customer reports. These annual costs should not be summed and should be considered individually as they may not all apply to each lab.

Based on the analysis, there is an estimated one-time cost incurred by labs of $1,000 and an estimated annual reoccurring costs of $500 would be incurred by labs. The minor cost thresholds are $10,606 for the 1% average annual payroll threshold and $7,878 for the .03% average annual receipts (sales) threshold. This shows that there are only minor costs incurred by labs to comply with the proposed rule changes, so no further analysis is required.

SECTION 5:
Determine whether the proposed rule may have a disproportionate impact on small businesses as compared to the 10 percent of businesses that are the largest businesses required to comply with the proposed rule.

Not applicable

SECTION 6:
If the proposed rule has a disproportionate impact on small businesses, identify the steps taken to reduce the costs of the rule on small businesses. If the costs cannot be reduced provide a clear explanation of why.

Not applicable

SECTION 7:

Describe how small businesses were involved in the development of the proposed rule.

Not applicable

SECTION 8: Job Impact

Identify the estimated number of jobs that will be created or lost as the result of compliance with the proposed rule.

Not applicable