pennsylvania
DEPARTMENT OF ENVIRONMENTAL PROTECTION

Bureau of Safe Drinking Water

COMMENT AND RESPONSE DOCUMENT

PFAS MCL Rule

25 Pa. Code Chapter 109
52 Pa.B. 1245 (February 26, 2022)
Environmental Quality Board Regulation #7-569
(Independent Regulatory Review Commission #3334)

Introduction

The Environmental Quality Board (Board) adopted the proposed per- and polyfluoroalkyl substances (PFAS) maximum contaminant level (MCL) rule at its November 16, 2021, meeting. On February 15, 2022, the Department of Environmental Protection (Department) submitted a copy of the proposed rulemaking to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the Senate and House Environmental Resources and Energy Committees for review and comment in accordance with Section 5(a) of Pennsylvania's Regulatory Review Act (71 P.S. § 745.5(a)). On February 26, 2022, the Board published the proposed rulemaking in the *Pennsylvania Bulletin* (52 Pa.B. 1245) with provision for a 60-day public comment period and five public hearings to accept verbal comments on the proposed regulation. The Board proposed to amend Chapter 109 (relating to safe drinking water) to establish MCLs and MCL Goals (MCLGs) for perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS). The proposed rulemaking also proposed to establish monitoring and reporting requirements for public water systems (PWSs) to demonstrate compliance with the MCLs, sampling and analytical requirements, and acceptable treatment technologies.

The public comment period opened on February 26, 2022, and closed on April 27, 2022. Five virtual public hearings were held on the proposed rulemaking as follows:

March 21, 2022, at 1 p.m.—2 p.m.
March 22, 2022, at 6 p.m.—8 p.m.
March 23, 2022, at 1 p.m.—2 p.m.
March 24, 2022, at 9 a.m.—11 a.m.
March 25, 2022, at 9 a.m.—11 a.m.

During the public comment period, the Board received more than 3,500 comments. Members of the General Assembly, the House Environmental Resources and Energy Committee, and the Independent Regulatory Review Commission (IRRC) submitted comments. Individuals representing the public, advocacy groups, and a variety of industries also provided comments on the proposed rulemaking.

The Board published notice of the public hearings in the *Pennsylvania Bulletin* and on the Department of Environmental Protection's website. The public hearings were held over a one-week period and were accessible via phone or internet connection. To maximize the public's access to, and participation in the hearings, the Board held one hearing each day of the week with start times in the morning, afternoon, and evening. All commentators who registered for the public hearings were able to testify. Over the five public hearings, the Board heard testimony from 29 individuals for a total of approximately five hours of testimony.

This document summarizes the written comments received during the public comment period and the testimony received at the public hearings. In assembling this document, the Department responded to all comments related to the PFAS MCL Rule proposed rulemaking. For the purposes of this document, comments of similar subject matter are grouped together and responded to accordingly. A list of the commentators, including name and affiliation, is provided in a separate document. The commentator list also includes identification numbers, which are referenced in parentheses following each comment in this document.

Copies of Comments

Copies of all comments received by the Board during the public comment period are posted on the Department's eComment website for this rulemaking:

https://www.ahs.dep.pa.gov/eComment/ViewComments.aspx?enc=DN064MT8R38NKyiRv2iU7Gugpg%2fnXc2%2f2obgquFY1IM%3d.

Additionally, copies of all comments received by the Board on this rulemaking are posted on IRRC's website at http://www.irrc.state.pa.us/regulations/RegSrchRslts.cfm?ID=3345.

Acronyms and Abbreviations used in this Comment and Response Document

ASDWA – Association of State Drinking Water Administrators
AWWA – American Water Works Association
ATSDR – Agency for Toxic Substances and Disease Registry
BAQ – Bureau of Air Quality
BAT – Best Available Technology
BCW – Bureau of Clean Water
BECB – Bureau of Environmental Cleanup and Brownfields
BIL – Bipartisan Infrastructure Law
BSDW – Bureau of Safe Drinking Water
BVRB – Bottled, Vended, Retail, and Bulk water systems
BWM – Bureau of Waste Management
CCR – Consumer Confidence Report
CDC – Centers for Disease Control
CDC MRL – CDC Minimal Risk Level
CDX – Central Data Exchange
CFR – Code of Federal Regulations
CWS – Community Water System
DBP – Disinfection Byproduct
DEP or Department – Pennsylvania Department of Environmental Protection
DOH – Pennsylvania Department of Health
DPAG – Drexel PFAS Advisory Group
DWELR – Drinking Water Electronic Lab Reporting
DWRS – Drinking Water Reporting System
DWSRF – Drinking Water State Revolving Fund
EJ – Environmental Justice
EJA – Environmental Justice Area
EJAB – Environmental Justice Advisory Board
EO – Executive Order
EP – Entry Point
EPA – United States Environmental Protection Agency
EQB – Environmental Quality Board
ERE – (House or Senate) Environmental Resources and Energy Committee
FRB – Field Reagent Blank
GAC – Granular Activated Carbon
GUDI – Groundwater Under the Direct Influence of Surface Water
HA – Health Advisory
HAL – Health Advisory Level
IIJA – Infrastructure Investment and Jobs Act
IRRC – Independent Regulatory Review Commission
IOC – Inorganic Chemical
IX – Anion Exchange
kg/L – kilograms per liter
LAP – Laboratory Accreditation Program
MCL – Maximum Contaminant Level

MCLG – Maximum Contaminant Level Goal
MDL – Method Detection Limit
MDH – Minnesota Department of Health
MDHHS – Michigan Department of Health and Human Services
mg/L – milligrams per liter
MGD – Million Gallons per Day
MRDL – Maximum Residual Detection Level
MRL – Minimum Reporting Level
µg/L – micrograms per liter
µg/mL – micrograms per milliliter
NAWC – National Association of Water Companies
ng/L – nanograms per liter
ng/mL – nanograms per milliliter
NOV – Notice of Violation
NPDWR – National Primary Drinking Water Regulation
NDWAC – National Drinking Water Advisory Council
NTNCWS – Nontransient Noncommunity Water System
O&M – Operation and Maintenance
PENNVEST – Pennsylvania Infrastructure Investment Authority
PFAS – Per- and polyfluoroalkyl substances
PFBA – Perfluorobutanoic acid
PFBS – Perfluorobutanesulfonic acid
PFHpA – Perfluoroheptanoic acid
PFHxA – Perfluorohexanoic acid
PFHxS – Perfluorohexanesulfonic acid
PFNA – Perfluorononanoic acid
PFOA – Perfluorooctanoic acid
PFOS – Perfluorooctanesulfonic acid
PFUnA – Perfluoroundecanoic acid
PN – Public Notice or Public Notification
ppt – Parts per Trillion
PSOC – Potential Source of PFAS Contamination
PUC – Public Utility Commission
PWS – Public Water System
RAA – Running Annual Average
RAF – Regulatory Analysis Form
RCRA – Resource Conservation and Recovery Act
RRA – Regulatory Review Act
SAB – Science Advisory Board
SDWA – Safe Drinking Water Act
SDWARS – Safe Drinking Water Accession and Review System
SMF – Standardized Monitoring Framework
SOC – Synthetic Organic Chemical
TAC – Public Water System Technical Assistance Center
TNCWS – Transient Noncommunity Water System
UCMR – Federal Unregulated Contaminant Monitoring Rule

UCMR3 – Third Federal Unregulated Contaminant Monitoring Rule
UCMR5 – Fifth Federal Unregulated Contaminant Monitoring Rule
VOC – Volatile (Synthetic) Organic Chemical

Independent Regulatory Review Commission, Legislative, and Federal Comments

1. **Comment:** IRRC noted that some commentators support regulating PFAS chemicals as a class, rather than individually. One commentator noted that numerous scientific institutions support grouping PFAS as a class given shared hazard traits and target the same health endpoint. One commentator stated that regulating PFAS "one at a time is not practical." Commentators pointed to the large number of compounds identified as PFAS as reason to regulate them as a class. IRRC requested that the Board explain the reasonableness of addressing PFOA and PFOS as individual compounds rather than as a class. (1, 34-38, 62, 92, 1107)

   Response: The Department acknowledges these comments, but, based on available data, has determined that regulating PFAS chemicals as individual compounds rather than as a class is reasonable, practical, and the preferred method. As noted in the preamble to the proposed rulemaking, the Department utilized the services of the Drexel PFAS Advisory Group (DPAG) through a toxicology services contract to: review other state and Federal agencies' work on MCLs; independently review the available data, science, and studies; and develop recommended MCLGs for select PFAS (EQB, 2022). As part of their review, DPAG noted that several states used a combined approach to regulating PFAS in drinking water; those states developed a drinking water standard that is a sum of several PFAS compounds. However, DPAG noted in their report that currently available scientific evidence does not appear to support a decision to use a cumulative or summative approach for regulating PFAS. Early in their review, DPAG determined that using a combined approach for a drinking water standard for PFAS appears to be a "shortcut based on a presumption that the agents all have similar health effects and endpoints" (DPAG, 2021). DPAG determined that it could not be assumed that all PFAS have shared hazard traits and target the same health endpoints, and that the best approach, which is most protective of public health, was to develop individual MCLGs for each PFAS requested by the Department, and the DPAG recommended that each PFAS compound be reviewed and MCLs determined individually. Furthermore, the occurrence data used by the Department in development of this rulemaking do not suggest a meaningful opportunity to regulate other PFAS compounds besides PFOA and PFOS, as explained in detail in Comment #25.

   Based on that determination and recommendation from DPAG, the Department moved forward with evaluating each PFAS individually to determine which to regulate and at what levels. The Department will also continue to review new information on other PFAS compounds as it becomes available and to consider whether to regulate additional PFAS in the future.

2. **Comment:** IRRC and some commentators noted PFAS limits were already established by other states. Some commentators stated that Pennsylvania should adopt those limits, particularly those of New Jersey. Several commentators also mentioned California's standards, and a few commentators mentioned other states' standards including Colorado, Connecticut, Massachusetts, Michigan, Minnesota, New Hampshire, New York, North Carolina, and Vermont. IRRC also noted that a commentator mentioned that Vermont, Maine, and Massachusetts all have MCLs for a sum of five or six different PFAS. (1, 5, 41, 45, 47, 56, 62, 94, 121, 148, 154, 157, 172, 2153)

   Response: The Department considered other states' limits when developing this rulemaking. As described in the preamble to the proposed rulemaking, the Department must follow a rigorous

rulemaking process when setting an MCL. In Pennsylvania, an MCL rulemaking must be based on an independent review of available data, studies, and science, and must consider all factors as required by the Federal Safe Drinking Water Act (Federal Act) (42 U.S.C.A. §§ 300f—300j-27) and the Commonwealth's Regulatory Review Act (RRA) (71 P.S. §§ 745.1—745.14). Among other things, the Department must consider health effects, occurrence data, technical limitations such as available analytical methods and detection and reporting limits, treatability of the contaminant and available treatment technologies, and costs and benefits (71 P.S. § 745.5b) (EQB, 2022).

Under a contract with the Department, DPAG reviewed the most currently available scientific studies and data, including other states' research and existing and proposed PFAS standards from across the country to inform the initial phase of the rulemaking process for establishing Pennsylvania drinking water standards. DPAG used that information to recommend MCLGs, as described in their report (DPAG, 2021). The Department utilized the MCLG recommendations in the process of establishing MCLs (see the Department's response to Comment #11 for a full explanation of the process to establish the proposed MCLs). At the time of the proposed rulemaking, six states had set MCLs for one or more PFAS—Massachusetts, Michigan, New Hampshire, New Jersey, New York, and Vermont. In addition, a few other states have set guidance values, action levels, response levels, or notification levels, including California, Connecticut, Minnesota, and Ohio; however, these alternate levels are not regulatory and do not carry the same enforceability as an MCL. While the proposed MCLs for the Commonwealth are slightly different from those established in other states, they are within the range and of comparable magnitude as the other state standards. This indicates that while the Department was required to follow the rulemaking process established in this Commonwealth, the end result of that process was a proposed rulemaking that includes MCLs for PFOA and PFOS at levels that are very similar to standards established independently by other states.

Regarding the states that have an MCL for a sum of PFAS, see the Department's response to Comment #1 on regulating PFAS as a class.

3. **Comment:** IRRC, the House Environmental Resources and Energy (ERE) Committee and several commentators raised concerns regarding the timing and alignment of this regulatory package and the forthcoming federal regulation. The House ERE Committee also expressed this concern, noting that "EPA's far greater resources will allow them to more accurately estimate the health impacts of an MCL, more accurately assess the water treatment technologies available to address PFAS, and more accurately estimate the cost of various treatment and monitoring systems to our water providers throughout the Commonwealth." The House ERE urged the Board to "rethink their approach and to defer to the EPA's experience and expertise to provide certainty to the regulated community." Commentators expressed concern with confusion among regulated entities over the two rulemakings, potential differences in the regulated levels or requirements of the two rulemakings, and the precedent of moving ahead of EPA with the rulemaking process. IRRC noted that commentators raised questions, including:

    - Has the Board engaged the EPA regarding the nearly simultaneous development of MCLs for PFOA and PFOS at the federal and state levels?

- Has the Board considered delaying implementation to avoid conflicting requirements and duplicate sampling?
- How will the Board address a situation where EPA's drinking water standards for PFOA and/or PFOS are either more stringent or less stringent than the Board's corresponding final standards for PFOA and/or PFOS?

IRRC requested that the Board address implementation concerns regarding the promulgation of potentially overlapping and potentially differing state and federal regulations related to PFOA and PFOS. IRRC also requested that the Board work with all parties with an interest in this rulemaking to create a regulatory environment that is consistent with the intent of the General Assembly, is reasonable, provides certainty to the regulated community, and is protective of the public health, safety, and welfare. (1, 2, 15, 17, 18, 26, 30, 60, 65, 66, 80)

Response: The Department has been following EPA's updates closely, has engaged with the EPA, and will continue to do so. At the same time, the Department has a responsibility to protect Pennsylvania's drinking water.

Safe drinking water is vital to maintaining healthy and sustainable communities. Proactively addressing PFOA and PFOS contamination in drinking water can reduce the incidence of illness and reduce health care costs. Recent research suggests the Combined Lifetime Health Advisory Level (HAL) for PFOA and PFOS of 70 ng/L, established by EPA in 2016, is not sufficiently protective against adverse health effects. The EPA has started the process of setting more stringent standards for PFOA and PFOS in drinking water, but that process is expected to take years to complete. Although EPA has stated a goal of publishing a final rulemaking by the fall of 2023 (US EPA, 2021b), EPA may not be able to meet that self-imposed deadline. Even if EPA meets that goal, there will be delayed implementation of the federal rule to allow states to incorporate the final federal regulation; so, the Department estimates future federal standards would not be effectively in place until fall of 2026 at the earliest. Given that timeline for federal standards, it is important that the Board act now to set more protective standards for this Commonwealth to protect the health of residents in this Commonwealth. Proper investment in public water system infrastructure and operations helps ensure a continuous supply of safe drinking water, enables communities to plan and build future capacity for economic growth, and ensures their long-term sustainability for years to come.

As stated in the preamble to the proposed rulemaking (EQB, 2022):

- PFAS are considered emerging contaminants because research is ongoing to better understand the potential impacts PFAS pose to human and animal health and the environment. PFAS are potentially linked to a number of adverse health effects, including high cholesterol, developmental effects including low birthweight, liver toxicity, decreased immune response, thyroid disease, kidney disease, ulcerative colitis and certain cancers, including testicular cancer and kidney cancer.

- In the absence of Federal action to address PFAS, Governor Tom Wolf signed Executive Order 2018-08 (EO) on September 19, 2018. The EO created the PFAS Action Team, a multi-agency group tasked with, among other things, developing a comprehensive response

to identify and eliminate sources of contamination, ensure drinking water is safe, manage environmental contamination, review gaps in data and oversight authority, and recommend actions to address those gaps. The PFAS Action Team released its Initial Report in December of 2019 to the Department's PFAS webpage. The report includes information about PFAS, challenges associated with managing contamination, actions taken to date and recommendations for future actions. Recommendations include additional funding for communities dealing with PFAS contamination and strengthened statutory authorities to adequately address PFAS.

- The amendments in this rulemaking are intended to protect public health by setting State MCLs for contaminants in drinking water that are currently unregulated at the Federal level. With these amendments, the Commonwealth would move ahead of EPA in addressing PFOA and PFOS in drinking water and join a group of states that have set MCLs for select PFAS in drinking water.

EPA has publicly stated its intent to publish a proposed PFAS National Drinking Water Regulation in December 2022, and final regulation in December 2023. While there are no guarantees EPA will publish a proposed rule as targeted in December 2022, when the proposed rule is published, the Department will review EPA's proposal and provide comments during the public comment period. As a basis for providing comments on a proposed federal rule, the Department will rely on the rigorous rulemaking process by which this rulemaking was developed, a process which demonstrates occurrence of PFAS in public water supplies and provides justification for the Department's proposed MCLs. Sometime after the closing of the comment period on EPA's proposed rulemaking, EPA will publish a final rule. Because a proposed federal rule has not yet been published, it is impossible to predict whether the EPA will adhere to its intended schedule and publish a final rule in December 2023. However, when a final federal rule is published, the regulations go into effect three years after they are finalized. During this three-year period, the Department will review the federal rule and evaluate the supporting documentation to determine how the federal rule compares to the Department's regulations. If the federal rule is more stringent, the Department will follow the Commonwealth's rulemaking process to revise its regulations to address any discrepancies and to ensure the Department's regulations meet at least the minimum federal requirements. If the final federal rule is less stringent than the Department's regulations, the Department will evaluate the federal rule and its supporting documentation to determine if any revisions are needed to the Department's regulations.

Setting MCLs ahead of EPA is expected to provide more timely protection of public health while imposing minimal additional regulatory requirements on the regulated community. Under this rulemaking, PWSs will be required to conduct monitoring for PFOA and PFOS earlier than may be required under federal regulations, and if levels are in violation of one or both MCLs, PWSs will be required to complete corrective actions sooner. If EPA ultimately sets MCLs that are less stringent, there may be some PWSs required to install treatment under this rule that would not have been required to under EPA's levels; however, through the rulemaking process, the Department has demonstrated that the MCLs in this rulemaking are in the interest of improved public health protection and reasonably balance costs and benefits. If EPA's MCLs are more stringent, there will likely be additional PWSs that will need to install treatment

beyond those that exceed the MCLs in this rulemaking. For the PWSs that install treatment as a result of a violation of the MCLs in this rulemaking, that treatment will put those PWSs in a better position to comply with EPA's MCLs regardless of whether they are more or less stringent. The approved treatment technologies in this rulemaking are capable of treating PFOA, PFOS, and other PFAS to non-detectable levels. If EPA's MCLs are more stringent, those PWSs that have installed treatment as required by this rulemaking may need to make relatively minor operational adjustments, such as changing out the media more frequently, but large-scale design changes are not expected.

Regarding EPA engagement, the Department notes that, in a letter dated April 26, 2022, received during the public comment period for the proposed rulemaking, EPA Region 3 Drinking Water Section offered support for the Department's PFAS regulatory efforts and provided comments regarding the proposed rule. Those comments are addressed in this Comment and Response Document (see Department responses to Comment #17, Comment #32, Comment #33, and Comment #34).

This rulemaking is also consistent with intent of the General Assembly. As it declared in the Pennsylvania Safe Drinking Water Act (SDWA), "[i]t is the purpose of this act to further the intent of section 27 of Article I of the Constitution of Pennsylvania by establishing a State program to assure the provision of safe drinking water to the public by establishing drinking water standards and developing a State program to implement and enforce the standards." 35 P.S. § 721.2(b). To ensure the residents of Pennsylvania are guaranteed an "adequate supply of safe, pure drinking water," the General Assembly charged the Board with the duty to adopt the rules and regulations of the Department "as it deems necessary for the implementation of the provisions of this act," which included granting the Board the authority to "adopt maximum contaminant levels or treatment technique requirements for any contaminant that a maximum contaminant level or treatment technique requirement has not been promulgated under the national primary and secondary drinking water regulations." 35 P.S. §§ 721.2(a) and 721.4(a).

In summary, it is the Department's position that in the interest of improved public health protection, it is imperative to move forward with this rulemaking at this time and not delay implementation. It is also the Department's position that this rulemaking is reasonable, will provide certainty to the regulated community by implementing an enforceable standard, and is protective of public health, safety, and welfare, consistent with the findings of the General Assembly in the SDWA. The Department remains committed to following the rulemaking process established by Pennsylvania law, which includes review by the General Assembly's standing committees. The Department also notes that, as part of that rulemaking process established by Pennsylvania law, the General Assembly's standing committees are represented on the Environmental Quality Board.

4. **Comment:** IRRC and some commentators noted that sampling for the EPA's Fifth Unregulated Contaminant Monitoring Rule (UCMR5) would occur simultaneously with initial monitoring requirements of this rulemaking. IRRC noted that commentators recommended that the Department allow UCMR5 monitoring data to be used for compliance with the initial monitoring period of the rulemaking. (1, 16, 17, 18, 28, 30)

Response: The Department agrees and has amended this final-form rulemaking. UCMR5 was published in the *Federal Register* on December 27, 2021 (US EPA, 2021c). The Department acknowledges the potential for duplicate sampling efforts for Pennsylvania's initial PFAS MCL compliance monitoring and UCMR5 sampling. To address this, the Department has amended the final-form rulemaking to include a clause in the initial monitoring requirements in § 109.301(16)(i) that allows for a modification of the timing of the initial monitoring period to coincide with UCMR5 monitoring.

It is important to note that it is the responsibility of the public water system (PWS) to ensure, if so desired by the PWS, that the schedules for Pennsylvania's initial PFAS MCL compliance monitoring and UCMR5 monitoring coincide, and to request a schedule change, if necessary, for either UCMR5 or Pennsylvania's initial PFAS MCL compliance monitoring, as described below. It is also important to note that not all water systems are required to conduct monitoring on a quarterly frequency for UCMR5, as is required for Pennsylvania's initial PFAS MCL compliance monitoring; it is the responsibility of the PWS to ensure that the minimum monitoring frequency is met.

For large water systems (>10,000 people), UCMR5 schedules can be modified in their CDX/SDWARS 5 account up to December 31, 2022, or by emailing UCMR_Sampling_Coordinator@epa.gov after December 31, 2022.

Small/medium water systems (≤10,000 people) conducting UCMR5 monitoring are required to use the laboratory predetermined by EPA for analysis, and EPA covers the cost of analysis, so no additional costs to small/medium water systems will be incurred if duplicate monitoring is conducted. Additionally, because EPA is the client of the laboratory for small/medium water systems under UCMR5, the lab may not be able to meet Pennsylvania reporting requirements to also report the data to the Department's Drinking Water Electronic Lab Reporting (DWELR) system for compliance monitoring. However, if a small/medium water system wishes to adjust their UCMR5 monitoring schedule, they must contact the EPA contractor for UCMR5 at UCMR5@glec.com or 1-800-949-1581 for schedule changes (before and/or after December 31, 2022).

For the same set of data to count toward both UCMR5 and Pennsylvania's initial PFAS MCL compliance monitoring, it must meet requirements of both rules. For Pennsylvania's initial PFAS MCL compliance monitoring, monitoring must be conducted according to all requirements in the rule (i.e., by a Pennsylvania accredited laboratory, using an approved method, reported appropriately and on time, etc.). For UCMR5, samples must be analyzed by the UCMR5-specified method by an EPA-approved laboratory for UCMR5 and must meet all requirements of the published UCMR5 (US EPA, 2021c). Therefore, if a PWS wishes to have the same data reported for both UCMR5 and Pennsylvania initial PFAS MCL compliance monitoring, it is the responsibility of the PWS to ensure that the monitoring schedules align, and that the lab conducting the analysis is both Pennsylvania accredited and UCMR5 approved, using an appropriate method, and is amenable to reporting the same data twice, including meeting Pennsylvania and UCMR5 reporting requirements.

As stated previously, the Department added a clause with the initial monitoring requirement in the final-form rule at § 109.301(16)(i) that allows a modification to the initial monitoring period to coincide with UCMR5 monitoring. This may allow some systems to realize cost savings by preventing duplicate analyses if they meet all requirements noted above to count as initial compliance monitoring. To modify the initial monitoring period, a PWS must request this change and the Department must approve it in writing. The Department will provide details on how to modify the initial monitoring schedule in guidance.

5. **Comment:** IRRC noted some commentators question whether there may be a shortage of certified laboratories to perform testing due to the overlap in timing of federal and state regulations. One commentator recommended the Department conduct "a more detailed logistical analysis … to ensure there is adequate lab capacity." The same commentator also recommended that the Department consider using the UCMR5 data for initial monitoring to alleviate concerns with lab capacity. IRRC requested that the Board provide information on the number and capacity of laboratories certified to perform required testing for implementation of the final regulation. (1, 17, 18, 30, 66)

   Response: Based on the Department's analysis, described below, there will be adequate laboratory capacity. Laboratory capacity for PFAS analysis was an important consideration in development of the rulemaking. There are three methods for PFAS analysis included in the rulemaking: EPA Method 533, EPA Method 537.1, and EPA Method 537 Version 1.1. As described in the preamble to the proposed rulemaking, the Department conducted a survey of laboratories accredited by Pennsylvania for analysis of PFAS by one or more of the three approved methods specified in the rule. The purpose of the survey was to collect data on laboratory capacity, services provided, analytical costs, and minimum reporting levels in order to assess the technical feasibility and analytical cost estimates of the rulemaking.

   The results of the survey conducted by the Department indicate more than sufficient capacity for compliance monitoring requirements of the PFAS MCL rule (PA DEP, 2021b). The Department requested information from 15 laboratories; of those, nine provided responses, five did not respond, and one responded that it had relinquished its accreditation. Of the nine that provided responses, no labs indicated that they are currently at capacity for accepting PFAS samples for analysis, meaning that they have capacity remaining to accept additional samples and not that they are operating at reduced capacity. Based on the responses, and considering each lab's maximum capacity for PFAS analyses and the percent of maximum capacity at which they were operating at the time of their response, remaining capacity for PFAS analysis by Pennsylvania-accredited laboratories was over 11,000 samples per month, or over 33,000 samples per quarter. Compliance monitoring under the rule will be required for 3,785 PWS entry points (EPs); even if the capacity calculations did not account for a field blank analysis for every sample, which would double the number of samples, survey results indicate more than sufficient capacity for every applicable EP to monitor quarterly, which is more monitoring than would be required at any one time. One of the nine laboratories alone indicated sufficient capacity for up to an additional 8,000 samples of all matrices per month for PFAS analysis. It is also important to note again that five laboratories did not respond to the survey; these five laboratories would likely provide additional capacity for PFAS analysis. Once this rulemaking is promulgated, it is also likely that more labs will seek Pennsylvania accreditation for one or more of the approved

methods as a result of the increased demand for PFAS analysis, which would expand overall analytical capacity.

In addition, initial quarterly monitoring for CWS and NTNCWS serving a population of more than 350 persons begins January 1, 2024, and initial quarterly monitoring for CWS and NTNCWS serving 350 or fewer persons begins January 1, 2025. This population breakdown was selected to evenly split initial monitoring across two years in order to better manage laboratory capacity and allow small systems more time to prepare for compliance monitoring.

Regarding the overlap of UCMR5 with initial compliance monitoring requirements for Pennsylvania's PFAS MCL Rule and the exacerbation of laboratory capacity issues associated with this overlap, the Department acknowledges this concern and agrees that the concurrent monitoring requirements may increase the burden on state-accredited laboratories. The Department received numerous comments on the overlap of UCMR5 with initial monitoring under the proposed PFAS MCL rulemaking; concern with laboratory capacity from this overlap was just one aspect of the comments received. The Department added language to the final rule to allow a PWS to request to modify their initial monitoring schedule, with written approval from the Department, to coincide with their UCMR5 schedule. Systems can also request to modify their UCMR5 schedule to coincide with their Pennsylvania PFAS MCL initial compliance monitoring schedule. Sample results meeting certain criteria can be reported as both UCMR5 data and Pennsylvania PFAS MCL initial compliance monitoring results. For sample results to be reported as both, they must be analyzed by a laboratory that is both Pennsylvania accredited and EPA approved for UCMR5, using a method that is both an approved method per the final-form Pennsylvania PFAS MCL rule and the appropriate method for UCMR5 monitoring, and results must be reported correctly and in the appropriate timeframe to meet both Pennsylvania reporting requirements and UCMR5 reporting requirements. (See the Department's response to Comment #4 on the overlap with UCMR5 monitoring.) Therefore, while survey results indicate more than enough laboratory capacity, allowing appropriately analyzed and reported results to count for both Pennsylvania PFAS MCL initial compliance monitoring and UCMR5 may help alleviate some of the analytical burden on state accredited labs.

6. **Comment:** IRRC and several commentators questioned the Department's cost estimates. One commentator noted that the basis for the cost estimates is not fully explained and questioned whether the sources of funding identified in the proposal will be sufficient to enable PWSs to afford the costs and whether PWSs will need to make rate adjustments to accommodate the additional costs. Another commentator questioned which data formed the basis for assuming that treatment costs are expected to be proportional to treatment plant capacity. IRRC requested the Board address these concerns and provide clarity regarding the fiscal impacts of treatment and monitoring. (1, 13-17, 19, 24, 26, 30, 59, 60, 66, 80, 152, 173)

   Response: First, the Department's basis for the cost estimates is fully explained in this response. Second, there are several funding sources available for PFAS treatment costs. The Pennsylvania Infrastructure Investment Authority's (PENNVEST's) Per- and Polyfluoroalkyl Substances Remediation Program currently is available to remediate PFAS contamination or presence in the water supply of public drinking water supply systems which are not related to

the presence of a qualified former military installation. More details on this program can be found on PENNVEST's website at: https://www.pennvest.pa.gov/Information/Funding-Programs/Pages/PFAS.aspx.

On November 15, 2021, the Infrastructure Investment and Jobs Act (IIJA) was signed into federal law. One component of the legislation is $4 billion nationally in Drinking Water State Revolving Fund (DWSRF) monies for projects to address emerging drinking water contaminants like PFAS and $5 billion nationally in grants to small and disadvantaged communities for projects addressing emerging drinking water contaminants like PFAS. Over five years, Pennsylvania's allocation of these IIJA funds is expected to be $116 million in DWSRF emerging contaminants funds and an additional $140.5 million in funding for projects addressing emerging drinking water contaminants in small and disadvantaged communities, for a total of $256.5 million. More details on this funding can be found on EPA's webpage at: https://www.epa.gov/infrastructure/fact-sheet-epa-bipartisan-infrastructure-law.

The estimates for capital costs of treatment installation and annual operation and maintenance (O&M) are explained in detail in the preamble to the proposed rulemaking. In summary, the average capital costs of the granular activated carbon (GAC) and anion exchange (IX) treatment is $3,370,735 per million gallons per day (MGD) per Entry Point (EP), with an average annual O&M costs $163,818 per MGD per EP (EQB, 2022).

Third, the data that formed the basis for assuming that treatment costs are expected to be proportional to treatment plant capacity came from a survey. Cost estimates are based on a survey of costs from vendors and systems that have installed PFAS treatment. The sizes of the treatment systems of respondents varied from 0.005 MGD to 2.88 MGD and costs for these systems ranged from approximately $47,000 to $3,250,000, respectively (PA DEP, 2021a). The survey provided information that showed generally lower capital and operational costs for smaller systems and increased costs as the volume of water treated increases; however, capital costs can vary greatly based on site-specific needs. Because of this variability and the limited cost information from available systems, a linear model for cost determination may not be accurate. Smaller systems may be more expensive to treat on a per gallon basis. Some systems may need infrastructure upgrades above and beyond the cost of the PFAS treatment, such as new well pumps, booster pumps, and buildings to house the treatment, whereas other systems may only need to purchase and install the PFAS treatment equipment and media. Estimating these costs more precisely would require essentially system-by-system analyses and assumptions about which systems will need to install PFAS treatment. Taking into account all these considerations, the Department believes that the cost estimates used in preparing this rulemaking are reasonable.

Any rate adjustments for ratepayers that PWSs make to recover costs associated with this rulemaking will depend on the specific costs for each PWS, as well as the type and availability of funding.

7. **Comment:** IRRC and a few commentators raised concerns regarding the byproducts of treatment technologies and disposal of the contaminants removed. IRRC requested that the

Board address implementation concerns related to byproducts of treatment technologies for PFAS removal. (1, 19, 30, 66)

Response: The Department considered three byproduct concerns when developing the proposed and final-form rulemaking. First, the Department requires a person to obtain a permit prior to constructing or modifying a public water system. This permitting process requires the water system to demonstrate it will properly dispose of any untreated PFAS-contaminated waters and spent media.

Second, industrial discharges, such as wastewater from drinking water treatment that contain PFAS wastes, would not be acceptable to discharge to an on-lot or municipal wastewater system. The Department's Clean Water Program is responsible for protecting and preserving the waters of the Commonwealth. This program includes requiring, and ensuring the effectiveness of, treatment systems that discharge to surface and ground water. Please refer to the Department's Bureau of Clean Water's wastewater management program webpage for more details: https://www.dep.pa.gov/Business/Water/CleanWater/WastewaterMgmt/Pages/default.aspx.

Third, all spent media will need to be disposed of at an appropriate landfill or an incinerator. The Department's Bureau of Waste Management (BWM) manages the permitting and inspection of hazardous, municipal, and residual waste generation, transportation, storage, beneficial use and disposal facilities, and administration of the municipal solid waste planning program, recycling program, resource recovery development program, and household hazardous waste program. Through researching and establishing viable disposal options, BWM will curb the PFAS pollution cycle by appropriately directing solid wastes containing PFAS through the proper channels for disposal, which will curb the cycle and prevent further environmental harm. Please refer to the Department's Bureau of Waste Management program webpage for more details: https://www.dep.pa.gov/Business/Land/Waste/Services/Pages/default.aspx.

8. **Comment:** IRRC and some commentators raised concerns about the costs and benefits of the proposed regulation. Commentators noted the benefits were not quantified or estimated in the proposed rulemaking, that the benefits were overstated, and the costs understated, and that the cost-effectiveness analysis was flawed. Commentators requested clarification on the basis for 90% as a goal for benefits, and on the conclusion that the MCLs for PFOA and PFOS represent a 90% and 93% increase in public health protection, respectively. Commentators assert that the basis for these figures and assumptions are not adequately explained. One commentator asserts that the benefits of setting MCLs at levels equal to the recommend MCLGs would vastly exceed costs. IRRC asked whether the cost/benefit of setting MCLs at MCLG levels was considered. IRRC requested that the Board address these concerns regarding the cost/benefit analysis, including clarifying the basis for selection of 90% as a goal. IRRC also requested that the Board explain how increasingly stringent drinking water values affect health outcomes and provide supporting data. IRRC also requested that the Board provide data for and explain the reasoning behind the assumption of linear improvement in health effects. (1, 31, 39, 47, 58, 64, 65, 69, 73, 80, 173)

Response: The costs and benefits are further explained below and in the preamble to this final-form rulemaking. The Department does not agree that the cost estimates are understated. These estimates are based on the information available to the Department at the time of the proposed rulemaking. The Department acknowledges that actual costs are likely to vary based on site-specific needs. For example, some systems may need infrastructure upgrades, such as new well pumps, booster pumps, and buildings to house new treatment, whereas other systems may only need to purchase and install the PFAS treatment equipment and media.

The Department conducted several surveys to gather information to estimate monitoring and treatment costs for this rulemaking. Surveys were conducted of: laboratories accredited in Pennsylvania for one or more analytical methods for PFAS (PA DEP 2021b); systems in Pennsylvania with existing PFAS removal treatment installed (PA DEP 2021a); PFAS removal treatment manufacturers; and members of the Association of State Drinking Water Administrators (ASDWA). Cost estimates were also informed by the Department's review of a PFAS case study published by the American Water Works Association (AWWA). The Department used the information gathered from the lab survey to consider available analytical methods, minimum reporting levels, laboratory capacity and analytical costs. The information gathered from the other surveys was used to evaluate treatment technologies and costs of installation and maintenance of treatment options. This information was also used with the occurrence data to conduct the cost and benefit analysis. Cost estimates for treatment installation and operation and maintenance, as well as for compliance monitoring, are explained in detail in the preamble to the proposed rulemaking (EQB, 2022).

In evaluating costs and benefits, the Department used the occurrence data to estimate treatment costs at the MCLGs, the 2016 EPA HAL of 70 ppt, and several values in between, including the MCLs (EQB, 2022).

To evaluate benefits, the Department assumed a linear relationship between health benefits at various MCL levels considered. As described in the preamble to the proposed rulemaking, the selection of a 90% reduction in adverse health effects as a goal for improved public health protection was intended to be consistent with other existing drinking water standards, including the requirement to achieve at least a 90% inactivation of *Giardia* cysts using disinfection processes within a filtration plant. Using this assumption and goal, the Department estimated that the MCL of 14 ppt for PFOA represents a 90% improvement in health protection, and the MCL of 18 ppt for PFOS represents a 93% improvement in health protection (EQB, 2022).

The Department believes that the cost-benefit data in the proposed rule was adequate; however, the Department acknowledges that the benefits were not quantified or monetized in order to conduct the cost-benefit analysis in the preamble to the proposed rulemaking. The Department also acknowledges that the assumption of a linear relationship between health benefits at various MCL levels was just that: an assumption. To provide additional information to support the cost-benefit analysis, the Department extended the contract with Drexel University and charged DPAG with estimating monetized benefits expected to be realized from implementation of the MCLs. The DPAG concluded that the proposed MCLs are predicted to have a significant economic benefit to Pennsylvania because the MCLs will reduce health care problems associated with PFAS (DPAG, 2022).

To predict the value of health care benefits, the DPAG used two approaches – the value transfer method and the counterfactual method. The value transfer method applies and scales quantitative estimates of health care impact costs from one study site to another. The counterfactual method assumes that reduction in exposure to PFOA and PFOS from drinking water will result in a health care cost benefit equal to estimated health care costs attributable to the base exposures to PFOA and PFOS. Although each of these methods has their limitations, it is possible to estimate projected savings from reducing exposure to PFOA and PFOS.

The DPAG's health care analysis was broken down into three steps: 1) testing whether the selected MCL will result in hypothetical serum levels known to be associated with disease specific critical effects identified by DPAG; 2) applying the counterfactual method to data derived from a study of a subpopulation of Pennsylvanians near a PFAS contaminated site to estimate health care benefits for that group; and 3) deriving a value transfer estimate from other health care impact studies.

The DPAG reviewed several studies that examined the exposure response relationship between PFOA levels and low birthweight. The authors of the Malits study selected a maternal serum level of 3.1 ng/mL as a reference level (Malits, 2018); below this level, the adverse health effects on low-birthweight infants would be reduced. The 3.1 ng/mL level also represents the upper limit of the lowest tertile in the study by Maisonet and colleagues (Maisonet, 2012) and represents the point above which statistically significant associations have been demonstrated when median serum or plasma levels during pregnancy were above approximately 3.1 ng/mL (Maisonet, 2012; Fei, 2011; Wu, 2012).

The DPAG utilized a serum PFAS calculator developed by Bartell to estimate blood serum concentrations of PFOA, based on an initial serum concentration and proposed levels of PFOA (Bartell 2017). The DPAG found that the model predicts that a woman of childbearing age would reach a steady-state PFOA serum level of 3.1 ng/mL if the consumed water was at the proposed MCL of 14 ng/L. Furthermore, the Bartell calculator confirms that the proposed MCL of 14 ng/L for PFOA is protective and is consistent with the Department's analysis that the MCL represents a 90% improvement in blood serum levels compared to the serum level predicted at the 2016 EPA HAL of 70 ng/L (DPAG, 2022). DPAG conducted a similar analysis for PFOS using data from the Grandjean (2012) study. The method developed by Bartell predicts that in women of childbearing age, the PFOS MCL of 18 ng/L would result in a steady-state serum level of 7.2 ng/L, which is below the lower bound of interquartile range and the geometric mean in mothers in the Grandjean study (DPAG, 2022). DPAG's review of PFAS blood serum levels at various PFAS concentrations in drinking water correlate well with the Department's assessment of at least 90% improvement of public health at the proposed MCLs.

Regarding the estimate of health care benefits, the DPAG noted that Malits (2018) estimated the total socioeconomic cost of PFOA-attributable low-birthweight births in the United States from 2003 through 2014 (11 years) was $13.7 billion. These costs included the direct hospital costs at the time of birth and lost economic productivity due to low-birthweight births being associated with longer-term outcomes such as lower lifetime earning potential. To determine what this would mean in Pennsylvania, the DPAG applied a value transfer method that assumes a scalable

relationship between impacts of PFOA-attributable low-birthweight births quantified by Malits in the total United States population. Since 4.0% of the United States population lives in Pennsylvania, the total costs for the entire statewide population due to low birthweight from PFOA exposure for the same period (2003 – 2014) are calculated to $548 million (approximately $637.58 million in 2022 dollars). To compare the costs and benefits to the Commonwealth's public water systems and the 11.9 million customers they serve, the DPAG estimated the total socioeconomic costs equate to $583 million in 2022 dollars. In other words, the PFOA MCL of 14 ng/L is estimated to result in health care cost savings of $583 million over a similar time period, or an average of $53 million annually.

Finally, the DPAG analyzed two additional studies to inform the estimated annual health care costs:

- In 2018, Nair studied communities near two former military bases in Pennsylvania that were exposed for several decades to PFAS through contaminated drinking water (Nair, 2021). The population in that community was estimated to be 84,000. Serum PFAS levels were compared with the national averages for 2013-2014 and their relationships with demographic and exposure characteristics were analyzed. The average levels of PFOA and PFOS among the study participants were 3.13 and 10.24 ng/mL, respectively. Overall, 75% and 81% of the study participants had levels exceeding the national average for PFOA (1.94 μg/L) and PFOS (4.99 μg/L), respectively. This study places these 2018 Pennsylvania communities in the same broad category as the 2003 National Health and Nutrition Examination Survey data for the United States population. A similar value transfer analysis suggests that the total health care costs associated with PFOA exposure in these Pennsylvania communities alone over a similar time period (11 years) would be $4.3 million in 2022 dollars. Assuming that PFAS levels fell in these Pennsylvania communities in the same manner that they fell nationally, the costs would average to $390,000 per year.

- A study by the Nordic Council of Ministers (2019) estimated the annual monetized impact of elevated mortality due to PFAS exposure ranged from $3.5 to $5.7 billion for a total population of 20.7 million people. Adjusted for the 11.9 million Pennsylvanian's served by public water, this produces a value transfer estimate of $2 to $3.3 billion. This suggests that PFAS contamination in drinking water may account for 2% to 3% of the annual health care costs in Pennsylvania, which are estimated by the Kaiser Family Foundation at $120 billion annually (KFF, 2022).

The Department does not agree that the benefits were overstated. The additional work conducted by DPAG clearly demonstrates the significant cost benefits from avoidance of adverse health effects expected from implementation of this rule. Utilizing the serum PFAS calculator developed by Bartell to estimate blood serum concentrations of PFOA and PFOS, the DPAG confirmed that the MCL of 14 ppt for PFOA would be a 90% improvement in blood serum levels compared to the serum level predicted at the 2016 EPA HAL of 70 ppt. DPAG's additional work also showed that blood serum levels would be expected to be lower from drinking water at the MCLG than at the MCL for both PFOA and PFOS (DPAG, 2022), which

demonstrates that increasingly stringent drinking water values (i.e., lower concentrations of PFAS in drinking water) are expected to result in improved health outcomes.

9. **Comment:** IRRC stated that commentators noted "conflicting toxicology information from an evolving state-of-the-science" and pointed to the fact that various approaches to regulating PFAS point to disagreement on what the standards should be. Commentators noted "Inadequacy of the Selected Toxicity Studies" and "conflicting toxicology information from an evolving state-of-the-science," and wrote that the critical studies identified by DPAG are "deeply flawed." IRRC also pointed out commentator questions including:

    - Were there documents (e.g. health, toxicological, epidemiological) that the Board reviewed, but for some reason, chose not to include in its evaluation process?

    - Is the EPA HAL unsafe for public drinking water?

    - Does the Board plan to review additional information that may not have been available during the time that the regulation was being drafted as it prepares the final-form regulation?

    IRRC also noted commentator questions regarding the expertise of the members of the Drexel PFAS Advisory Group and their selection of toxicological studies, and question whether members of the DPAG have sufficient expertise in the toxicological properties of PFAS or with regulatory risk assessment. IRRC requested that the Board address concerns related to acceptable data, and explain how the data supporting the final regulation protects the public health, safety, and welfare. IRRC also requested that the Board explain how standards may be revised in the future based on improved scientific understanding about exposure, dose, and toxicology. IRRC also requested that the Board address concerns related to the source of data and basis for the MCL standards in the final-form regulation, and explain how the data provided as the basis for the final regulation is acceptable. (1, 18, 63, 64, 65)

    Response: The Department agrees that the scientific research, data, and studies on PFAS are continually evolving. The Department also agrees that there is inherent variability and uncertainty in the field of toxicology. There are numerous variables, including the selection of health-based endpoints and critical studies, different models for determining reference doses, assumptions in applying animal studies, estimating relative source contribution, and other uncertainty factors, that can lead to wide variability in calculated outcomes. However, the Department does not believe that this inherent variability or the evolving research means that it is not possible to develop an effective regulation that is scientifically derived and that will provide improved public health protection.

    As noted in the preamble to the proposed rulemaking, an MCL rulemaking must be based on available data, studies, and science, and must consider all factors as required by the Federal Safe Drinking Water Act (Federal Act) (42 U.S.C.A. §§ 300f—300j-27) and the Commonwealth's Regulatory Review Act (RRA) (71 P.S. §§ 745.1—745.14). Among other things, the Department must consider health effects, occurrence data, technical limitations such as available analytical methods and detection and reporting limits, treatability of the contaminant and

available treatment technologies, and costs and benefits (71 P.S. § 745.5b) (EQB, 2022). See the Department's response to Comment #11 for a description of the MCL rulemaking process.

As explained in the preamble to the proposed rulemaking, the Department executed the Toxicology Services Contract with Drexel University in December 2019 to review current scientific studies and data on the health effects of PFAS and provide recommended maximum contaminant level goals (MCLGs), which are the basis for setting maximum contaminant levels (MCLs) (EQB, 2022). The Drexel PFAS Advisory Group (DPAG) is comprised of a group of medical toxicologists as well as experts in the fields of environmental engineering and public health. The DPAG includes three Board Certified Toxicologists and MDs in the College of Medicine, two PhDs from the College of Engineering, and three additional staff, including a PhD in the Academy of Natural Sciences, and MD in the College of Medicine, and an MSPH in the School of Public Health. Deliverables from the toxicology contract include the "Drexel PFAS Workbook" (PFAS Workbook) and the report "Maximum Contaminant Level Goal Drinking Water Recommendations for Per- and Polyfluoroalkyl Substances (PFAS) in the Commonwealth of PA" (MCLG Report). The credentials of the group's members are included in Appendix A of the MCLG Report (DPAG, 2021).

In determining recommended MCLGs, the DPAG used an evidence-based approach to independently review the available studies and to select critical health effects and critical studies for the PFAS evaluated. The scientific studies reviewed by the DPAG, including their strengths and weaknesses, are discussed fully and cited in the PFAS Workbook and MCLG Report (DPAG, 2020; DPAG, 2021). References reviewed by the Department, including the DPAG deliverables, are cited in the final-form rulemaking documents. DPAG provided substantial justification in the MCLG Report for the selection of critical health effects and critical studies, based on the extensive expertise of the group. Specifically, DPAG identified the target population for PFOA and PFOS as infant exposure via breastmilk for 1 year, from mother chronically exposed via water, followed by lifetime exposure via drinking water. All scientific studies have some limitations, and the strengths and weaknesses of the selected studies are discussed fully in the MCLG Report (DPAG, 2021). The application of uncertainty factors is the method additionally used to offset uncertainties and limitations in the available scientific evidence.

The calculation of the MCLGs employed the transgenerational toxicokinetic model developed by Goeden and differs from the typical formula for adults or infants (DPAG, 2021). This model provided the best insight into the exposure pathways for the target population. The Department used the MCLG recommendations from the MCLG Report as the basis for development of MCLs.

In addition to the Toxicology Services Contract, the Department's Safe Drinking Water Program developed and implemented the PFAS Sampling Plan to prioritize PWS sites for PFAS sampling and generate statewide occurrence data (PA DEP, 2019; PA DEP, 2021c). That occurrence data was extrapolated across all applicable PWSs and EPs and was ultimately used to inform the decision on which PFAS to regulate and to estimate the number of PWSs that may potentially have levels of PFAS exceeding various MCL levels.

To assess the technical limitations such as available analytical methods and detection and reporting limits along with treatability and treatment technology considerations, the Department conducted several surveys to gather information. Surveys were conducted of laboratories accredited in Pennsylvania for one or more analytical methods for PFAS, systems in Pennsylvania with existing PFAS removal treatment installed, PFAS removal treatment manufacturers, and members of the ASDWA (PA DEP, 2021a; PA DEP, 2021b). Assessment of technical limitations was also informed by the Department's review of a PFAS case study published by the AWWA. The Department used the information gathered from the lab survey to consider available analytical methods, minimum reporting levels, laboratory capacity, and analytical costs. The information gathered from the other surveys and review of the AWWA-published case study was used to evaluate treatment technologies and costs of installation and maintenance of treatment options. This information was also used along with the occurrence data to conduct the cost and benefit analysis.

In summary, the rule is designed to improve public health protections for Pennsylvanians based on scientific studies and data available at the time the rulemaking was developed. Independent review of the available science and MCLG recommendations were provided by DPAG, a panel of experts in the fields of medical toxicology, public health, and environmental engineering. References reviewed and used by the Department in development of the proposed rulemaking are cited in Section D of the preamble to the proposed rulemaking. Current research indicates that the 2016 EPA Combined Health Advisory Level (HAL) of 70 ng/L for PFOA and PFOS is not sufficiently protective of public health. Implementing the MCLs will provide an increased measure of public health protection by resulting in lower levels of PFOA and PFOS in drinking water provided to PWS customers in Pennsylvania. Therefore, it is the Department's position that it is imperative to move forward at this time with this rulemaking in the interest of improved public health protection. The Department will continue to review and evaluate emerging science and recommendations from experts in the field of toxicology, including recommendations from EPA's Science Advisory Board, and the Department will consider future revisions to this rule as deemed necessary. If the Department determines that revisions to this rule are needed in the future, the Department will initiate and follow Pennsylvania's rulemaking process (see the Department's response to Comment #3 for additional information on how the Department may revisit this rule based on future EPA actions).

10. Comment: IRRC and a commentator questioned whether the Department sought additional independent peer review of the conclusions set forth in the proposed regulation. (1, 17)

Response: As detailed below, the Department sought independent peer review from DPAG of the available science and the Department consulted with the Department's drinking water advisory committee at both the proposed stage and the final-form stage. As part of the Department's PFOA MCL rulemaking petition recommendation, the DPAG report and workbook were first made publicly available on June 1, 2021, when the meeting materials for the June 15, 2021 Board meeting were posted on the Board website. The DPAG report and workbook were included again in the proposed rulemaking when it was posted on the Board's website on November 2, 2021, for consideration at the Board's November 16, 2021 meeting. The DPAG report and workbook were discussed and cited prominently in the preamble to the proposed rulemaking, including links to the full reports, which provided additional opportunity

for peer review during the 60-day public comment period, which began when the proposed rulemaking was published in the *Pennsylvania Bulletin* on February 26, 2022. The Department also followed the regulatory development process required by Pennsylvania law, which includes rigorous internal and external review stages. More detail about these steps is provided below.

The Department contracted with Drexel University to: review other state and Federal agency work on MCLs; independently review the data, science, and studies; and develop recommended MCLGs for select PFAS. MCLGs are the starting point for determining MCLs. The Drexel PFAS Advisory Group (DPAG) reviewed pertinent literature and work across the country and independently developed recommended MCLGs based on non-cancer endpoints. DEP also received input on setting appropriate MCLs from a toxicologist with the Pennsylvania Department of Health.

After developing the draft proposed rulemaking language, the Department shared it with the Department's drinking water advisory committee, the Public Water System Technical Assistance Center (TAC) Board on July 29, 2021. The TAC Board reviews and comments on proposed DEP regulations that affect public water systems. The TAC Board consists of representatives from various organizations, including the Pennsylvania Rural Water Association, the Pennsylvania Municipal Authorities Association, the AWWA – Pennsylvania Chapter, the Water Works Operators Association of Pennsylvania, the Pennsylvania Manufactured Housing Association, the Pennsylvania State Association of Township Supervisors, Rural Community Assistance Partnership, the Office of Consumer Advocate, the Pennsylvania Chapter of the National Association of Water Companies, and the Pennsylvania State Association of County Commissioners, as well as members from public interest and environmental organizations and members from building and land development interests. In a letter dated July 30, 2021, the TAC Board offered their support of the Department in the rulemaking process and recommended that the Department move forward with the rule to present to the Board as a proposed rulemaking.

The Department presented the proposed rulemaking to the Board at the November 16, 2021, meeting. After adoption by the Board, the proposed regulation was published in the *Pennsylvania Bulletin* on February 26, 2022, for a 60-day public comment period (EQB, 2022). During the public comment period, the Department hosted five public hearings on the proposed regulation during the week of March 21, 2021. The Department received testimony from 29 individuals during the hearings, which are addressed in this comment and response document along with comments the Department received from over 3,500 commentators, including several legislators, the House Environmental Resources and Energy committee, and the Independent Regulatory Review Commission (IRRC).

The Department reviewed all comments and testimony received during the comment period and developed responses to those comments, which are included in this comment and response document. In response to some comments, the Department revised the proposed rulemaking.

After incorporating revisions based on public comments, the Department consulted with the TAC Board draft final-form rulemaking on July 14, 2022. The TAC Board supported the Department moving forward to present the final-form rulemaking to the Board.

Also see the Department's response to Comment #9 for discussion of the public health benefits of moving forward with this rulemaking now and how the Department will continue to review and evaluate emerging science and recommendations and will consider future revisions to this rule as deemed necessary.

11. **Comment:** IRRC noted that several legislators and numerous commentators suggested the proposed MCLs should be lower, but did not cite to specific toxicological or scientific studies to support the lower numbers. Some of these commentators expressed a general request for lower MCLs, and some suggested specific lower numbers to consider, including zero; not detected; 1 ppt for total PFAS; 1ppt up to 6ppt for PFOA and no more than 5ppt for PFOS; below 6ppt for both PFOS and PFOA; 6 ppt for PFOA, 5 ppt for PFOS, and 13 ppt combined; and no higher than the recommended MCLGs (8 ppt for PFOA and 14 ppt for PFOS). Some commentators also noted that the reason for lower MCLs should be for the protection of infants and young children, who are the most vulnerable to the effects of PFAS. IRRC requested that the Board address these concerns and explain how it determined that the MCLs for PFOA and PFOS in the final regulation protect the health, safety, and welfare of children, particularly young children. (1, 4, 5, 10, 11, 22, 31, 41, 42, 46, 50, 51, 53-55, 58, 62, 67-79, 84, 88, 91, 93, 102, 108, 109, 112-115, 117, 123-125, 129-132, 140, 141, 143, 145-147, 151, 157, 158, 160, 162, 164, 165, 168, 174-1053, 1087-1090, 1092-1106, 1108-1121, 1123-2125, 2130, 2139, 2145, 2150, 3132-3560)

    Response: As explained in the preamble to the proposed rulemaking, the Department is required to follow a rigorous process when setting an MCL. An MCL rulemaking must be based on available data, studies, and science, and must consider all factors as required by the Federal Safe Drinking Water Act (Federal Act) (42 U.S.C.A. §§ 300f—300j-27) and the Commonwealth's Regulatory Review Act (RRA) (71 P.S. §§ 745.1—745.14). Among other things, the Department must consider health effects, occurrence data, technical limitations such as available analytical methods and detection and reporting limits, treatability of the contaminant and available treatment technologies, and costs and benefits (71 P.S. § 745.5b) (EQB, 2022).

    In addition to State requirements, the Department needs to consult the Federal Act and its implementing regulations. See 42 U.S.C.A. §§ 300f—300j-9; see also 40 CFR Parts 141, 142 and 143 (relating to National Primary Drinking Water Regulations; National Primary Drinking Water Regulations Implementation; and Other Safe Drinking Water Act Regulations). The EPA explains how the agency sets standards at the following link: www.epa.gov/sdwa/how-epa-regulates-drinking-water-contaminants. In establishing the MCLs in this rulemaking, the Department was informed by the EPA's procedure to establish an MCL. It is important for the Department to understand the EPA's process of setting an MCL, because similar criteria are required of the Department under the Commonwealth's RRA, and because the MCLs in this rulemaking are the first MCLs that the Department has set; every other MCL in effect in this Commonwealth was set by the EPA and incorporated by reference into the Department's Chapter 109 regulations. In addition, to retain primacy for implementing the Federal Act in this Commonwealth, the Department's standard setting process must be at least as stringent as the Federal process.

The first step in setting an MCL is determining an appropriate maximum contaminant level goal (MCLG). Once the MCLG is determined, the EPA sets an enforceable standard. In most cases, the standard is an MCL. The MCL is set as close to the MCLG as feasible. The EPA must take cost into consideration in determining the feasible MCL. As a part of the rule analysis, the Federal Act requires the EPA to prepare a health risk reduction and cost analysis in support of any standard. The EPA must analyze the quantifiable and nonquantifiable benefits that are likely to occur as the result of compliance with the proposed standard. The EPA must also analyze increased costs that will result from the proposed drinking water standard. In addition, the EPA must consider incremental costs and benefits associated with the proposed alternative MCL values. Where the benefits of a new MCL do not justify the costs, the EPA may adjust the MCL to a level that maximizes health risk reduction benefits at a cost that is justified by the benefits.

Proposed MCLGs for PFOA and PFOS

In December 2019, the Department's Safe Drinking Water Program executed a toxicology services contract with Drexel University to: review other state and Federal agency work on MCLs; independently review the data, science, and studies; and develop recommended MCLGs for select PFAS. Deliverables were completed in January 2021 and include the "Drexel PFAS Workbook" and "MCLG Drinking Water Recommendations for PFAS in the Commonwealth of PA" (MCLG Report). The MCLG Report was developed by the Drexel PFAS Advisory Group (DPAG)—a multidisciplinary team of experts in toxicology, epidemiology, drinking water standards and risk assessment. The DPAG reviewed pertinent literature and work across the country and independently developed recommended MCLGs based on non-cancer endpoints. The MCLG Report discusses relevant inputs and includes a summary table for each PFAS that documents the development of the recommended MCLG.

After a literature search and a review of the available evidence and recommendations from various agencies, the DPAG developed an MCLG recommendation for PFOA of 8 ng/L or ppt and for PFOS of 14 ng/L or ppt, based on non-cancer endpoints (DPAG, 2021). For PFOA, the DPAG determined that the most relevant inputs were from the EPA, ATSDR, Minnesota Department of Health (MDH), New Jersey Department of Environmental Protection, and Michigan Department of Health and Human Services (MDHHS). The DPAG selected Koskela, et al. (2016) and Onishchenko, et al. (2011) as the critical studies for PFOA, which identified developmental effects (including neurobehavioral and skeletal effects) as critical. For PFOS, the DPAG referenced inputs from the EPA, ATSDR, MDH, and MDHHS. The DPAG selected Dong, et al. (2011) as the critical study for PFOS, which identified immunotoxicity effects (including immune suppression) as critical. In summary, the DPAG recommended a chronic non-cancer MCLG for PFOA of 8 ng/L or ppt and for PFOS of 14 ng/L or ppt to protect breast-fed infants and throughout life. The MCLG recommendations for PFOA and PFOS of 8 and 14 ng/L or ppt, respectively, were included in the proposed rulemaking as proposed MCLGs and were the basis for development of the proposed MCLs (EQB, 2022).

PFOA — MCL of 14 ng/L

The MCL of 14 ng/L for PFOA is based on the health effects and MCLG, occurrence data, technical feasibility, and costs and benefits.

A review of occurrence data indicates that 25 EPs out of a total number of 435 EPs sampled exceeded the MCL for PFOA of 14 ng/ L (PA DEP, 2021c). This represents 5.7% of all EPs sampled. This exceedance rate may overestimate the exceedance rate for other PWSs in this Commonwealth that were not sampled because the occurrence data sampling predominately targeted sites near potential sources of PFAS contamination. However, the occurrence data provides the most relevant information currently available on the prevalence and levels of PFAS in PWSs in this Commonwealth. Applying the occurrence data PFOA MCL exceedance rate (5.7%) to the total number of EPs for all applicable PWSs (3,785 EPs), it is estimated that 218 EPs will exceed the MCL of 14 ng/L.

In evaluating the costs and benefits, the Department compared costs for several possible values for the MCL, including the 2016 EPA combined HAL of 70 ppt, the MCLG, and several levels in between. Treatment cost estimates were determined based on a survey conducted of systems in this Commonwealth with existing PFAS treatment and of PFAS treatment manufacturers, an AWWA-published PFAS Case Study, and from information provided by members of the ASDWA. Treatment cost estimates are based on the costs to install and maintain treatment for a 1-MGD treatment plant. The actual costs would be expected to be less for a treatment plant with a smaller design capacity. Compared to the 2016 EPA HAL of 70 ng/L, the Department estimates that the MCL of 14 ng/L for PFOA would result in a 253% increase in annual costs (EQB 2022). See the preamble to the proposed rule for full explanation of cost estimates.

The Department's goal is to provide at least a 90% reduction in adverse health effects (a 90% improvement in health protection) when compared to the 2016 EPA HAL of 70 ng/L. This goal is consistent with several existing drinking water standards. As noted in the preamble to the proposed rule, the estimated benefits expected from the MCL for PFOA of 14 ng/L is 90% improvement in health protection as compared to the 2016 EPA HAL of 70 ppt (EQB, 2022).

The Department believes that the MCL for PFOA of 14 ng/L strikes an appropriate balance between the benefits (90% improvement in public health) and costs (253% increase in costs) when compared to the benefits and costs associated with meeting the HAL of 70 ng/L.

Regarding technical feasibility, it is the Department’s assessment that analytical methods and laboratory capacity exist for water systems to be able to demonstrate compliance with the MCL for PFOA. With the minimum reporting level (MRL) of 5 ng/L in the rulemaking, the lowest MCL technically feasible would be 6.5 ng/L, which would allow for analytical error of +/- 30% in reported results. The MRL of 5 ng/L is based on a survey of laboratories accredited to analyze PFAS by the specified methods. The MRL is set at a level that is low enough to allow PWSs to demonstrate compliance with the MCL, but high enough that laboratories can consistently and accurately report results at or below that level. It is not feasible to set an MCL at “zero” or “not detected” as some commentators suggested, because limits of detection can vary from one laboratory to another, and because they can change over time as new analytical

methods are developed. Treatment technologies also exist for water systems to attain compliance if PFOA levels exceed the MCL. Approved analytical methods and acceptable treatment technologies are included in this rulemaking.

PFOS—MCL of 18 ng/L

The MCL of 18 ng/L for PFOS is based on the health effects and MCLG, occurrence data, technical feasibility, and costs and benefits.

A review of occurrence data indicates that 22 EPs out of a total number of 435 EPs sampled exceeded the MCL for PFOS of 18 ng/L (PA DEP, 2021c). This represents 5.1% of all EPs sampled. This exceedance rate may overestimate the exceedance rate for other PWSs in this Commonwealth that were not sampled because the occurrence data sampling predominately targeted sites near potential sources of PFAS contamination. However, the occurrence data provides the most relevant information currently available on the prevalence and levels of PFAS in PWSs in this Commonwealth. Applying the occurrence data PFOS MCL exceedance rate (5.1%) to the total number of EPs for all applicable PWSs (3,785 EPs), it is estimated that 191 EPs will exceed the MCL of 18 ng/L.

In evaluating the costs and benefits, the Department compared costs for several possible values for the MCL, including the 2016 EPA combined HAL of 70 ppt, the MCLG, and several levels in between. Treatment cost estimates were determined based on a survey conducted of systems in this Commonwealth with existing PFAS treatment and of PFAS treatment manufacturers, an AWWA-published PFAS Case Study and from information provided by members of the ASDWA. Treatment cost estimates are based on the costs to install and maintain treatment for a 1-MGD treatment plant. The actual costs would be expected to be less for a treatment plant with a smaller design capacity. Compared to the 2016 EPA HAL of 70 ng/L, the Department estimates that the MCL of 18 ng/L for PFOS would result in a 94% increase in annual costs (EQB, 2022). See the preamble to the proposed rule for full explanation of cost estimates.

The Department's goal is to provide at least a 90% reduction in adverse health effects (a 90% improvement in health protection) when compared to the HAL of 70 ng/L. This goal is consistent with several existing drinking water standards. As noted in the preamble to the proposed rule, the estimated benefits expected from the MCL for PFOS of 18 ng/L is 93% improvement in health protection as compared to the 2016 EPA HAL of 70 ppt (EQB, 2022).

The Department believes that the MCL for PFOS of 18 ng/L strikes a balance between the benefits (93% improvement in public health) and costs (94% increase in costs) when compared to the benefits and costs associated with meeting the HAL of 70 ng/L.

Regarding technical feasibility, it is the Department’s assessment that analytical methods and laboratory capacity exist for water systems to be able to demonstrate compliance with the MCL for PFOS. With the minimum reporting level (MRL) of 5 ng/L in the rulemaking, the lowest MCL technically feasible would be 6.5 ng/L, which would allow for analytical error of +/- 30% in reported results. The MRL of 5 ng/L was based on a survey of laboratories accredited to analyze PFAS by the specified methods. The MRL was set at a level that is low enough to allow

public water systems to demonstrate compliance with the MCL, but high enough that laboratories can consistently and accurately report results at or below that level. It is not feasible to set an MCL at "zero" or "not detected" as some commentators suggested, because limits of detection can vary from one laboratory to another, and because they can change over time as new analytical methods are developed. Treatment technologies also exist for water systems to attain compliance if PFOS levels exceed the MCL. Approved analytical methods and acceptable treatment technologies are included in this rulemaking.

State data

The Department also reviewed work done in other states to regulate PFAS in drinking water. At the time the proposed rulemaking was developed, six other states had set MCLs for select PFAS, including PFOA and PFOS, as summarized in the below table. The MCLs for the Commonwealth are of comparable magnitude as the other state standards.

State	NY	MI	NJ	NH	PA	MA	VT
PFOA MCL (ng/L)	10	8	14	12	14	20*	20*
PFOS MCL (ng/L)	10	16	13	15	18	20*	20*

*The MCLs for MA & VT are for a group of 5 (VT) or 6 (MA) PFAS, including PFOA and PFOS (not individual contaminants).

Protection of children and infants

The MCLG recommendations provided by DPAG in the MCLG Report were based on a literature search and a review of the available evidence and recommendations from various agencies. By definition in the National Primary Drinking Water Regulations in 40 CFR Part 141, an MCLG is "the maximum level of a contaminant in drinking water at which no known or anticipated health effect on the health of persons would occur, and which allows an adequate margin of safety" (§ 141.2 Definitions). As noted in the MCLG Report, the DPAG was charged with developing recommended MCLGs at concentrations that were focused solely on protection of human health. The DPAG identified the target population for PFOA and PFOS as infant exposure via breastmilk for 1 year, from mother chronically exposed via water, followed by lifetime of exposure via drinking water. The calculation of the MCLG employed the transgenerational toxicokinetic model developed by Goeden and differs from the typical formula for adults or infants. This model provided the best insight into the exposure pathways for the target population. Thus, DPAG noted in the MCLG Report that the recommended MCLGs for PFOA and PFOS are at levels intended to "protect breastfed infants and throughout life" (DPAG, 2021).

As noted previously, to develop MCLs from these MCLGs, which are protective of infants and children, the Department was required to follow the strict regulatory process, which includes the cost-benefit analysis. While the MCLs are slightly higher than the MCLGs, the Department does not believe that the significantly higher cost estimates for lower MCLs were justified. The MCLs are of the same magnitude and within the range as other states' standards, and – consistent with several existing drinking water standards – they provide at least a 90% improvement in health protection compared to implementation of the 2016 EPA HAL. Further,

when compared to other federal standards where the MCL is set higher than the MCLG, these MCLs are within the same range of increase from the MCLG. Infants and children will benefit from improved health protection from implementation of the MCLs compared to the 2016 EPA HAL.

The DPAG utilized a serum PFAS calculator developed by Bartell to estimate blood serum concentrations of PFOA, based on an initial serum concentration and proposed levels of PFOA (Bartell 2017). The DPAG found that the model predicts that a woman of childbearing age would reach a steady-state PFOA serum level of 3.1 ng/mL if the consumed water was at the proposed MCL of 14 ng/L. Furthermore, the Bartell calculator confirms that the proposed MCL of 14 ng/L for PFOA is protective and is consistent with the Department's analysis that the MCL represents a 90% improvement in blood serum levels compared to the serum level predicted at the 2016 EPA HAL of 70 ng/L (DPAG, 2022). DPAG conducted a similar analysis for PFOS using data from the Grandjean (2012) study. The method developed by Bartell predicts that in women of childbearing age, the PFOS MCL of 18 ng/L would result in a steady-state serum level of 7.2 ng/L, which is below the lower bound of interquartile range and the geometric mean in mothers in the Grandjean study (DPAG, 2022). DPAG's review of PFAS blood serum levels at various PFAS concentrations in drinking water correlate well with the Department's assessment of at least 90% improvement of public health at the proposed MCLs.

12. **Comment:** IRRC noted that legislators and many commentators suggested that the proposed MCLs should be lower in order to be more protective of children. Many of these commentators including some legislators point to a toxicological analysis and recommendations from Cambridge Environmental Consulting (CEC). These commentators would like the PFOA MCL to be 1 ppt but not to exceed 6 ppt, and the PFOS MCL no greater than 5 ppt, according to the CEC's recommendations. IRRC requested that the Board address these concerns, which seem to indicate that the Board's proposed levels would not be protective of children. (1, 9, 32-34, 37, 39, 40, 43-45, 47-49, 61, 70, 71, 73, 89, 92, 154, 164, 1050-1079, 2126-2129, 2131-2138, 2140-2144, 2146-2149, 2151-2776)

    Response: The recommendations from Cambridge Environmental Consulting cited by some commentators only considered health effects and did not consider the other factors required to be considered in setting an MCL, which are discussed in more detail below.

    The Drexel PFAS Advisory Group (DPAG) identified the target population for PFOA and PFOS as infant exposure via breastmilk for 1 year, from mother chronically exposed via water, followed by lifetime of exposure via drinking water. The calculation of the MCLG employed the transgenerational toxicokinetic model developed by Goeden and differs from the typical formula for adults or infants. This model provided the best insight into the exposure pathways for the target population. All studies have some limitations, and the strength and weaknesses of the selected studies are discussed fully in the "Maximum Contaminant Level Goal Drinking Water Recommendations for Per- and Polyfluoroalkyl Substances (PFAS) in the Commonwealth of Pennsylvania" (MCLG Report), prepared by DPAG (DPAG, 2021). The application of uncertainty factors is the method additionally used to offset inadequacies in the evidence. See the Department's response to Comment #9 for a discussion of the scientific studies and data used in the rulemaking process.

As explained in the preamble, the Department is required to follow a rigorous process when setting an MCL. An MCL rulemaking must be based on available data, studies, and science, and must consider all factors as required by the Federal Safe Drinking Water Act (Federal Act) (42 U.S.C.A. §§ 300f—300j-27) and the Commonwealth's Regulatory Review Act (RRA) (71 P.S. §§ 745.1—745.14). Among other things, the Department must consider health effects, occurrence data, technical limitations such as available analytical methods and detection and reporting limits, treatability of the contaminant and available treatment technologies, and costs and benefits (71 P.S. § 745.5b) (EQB, 2022).

The MCLG recommendations provided by DPAG in the MCLG Report were the starting point for development of MCL. After consideration of all relevant factors as noted above, the Department determined that the MCLs strike an appropriate balance between the public health benefits and the implementation costs. See the Department's response to Comment #11 for a description of the MCL rulemaking process.

13. **Comment:** IRRC noted that legislators and many commentators assert that the final rulemaking should be implemented immediately upon finalization. Many commentators stated that water systems should be required to start sampling immediately because otherwise it will be another two to three years before verifiably clean drinking water is available. IRRC requested that the Board explain how it determined that the effective dates in the final regulation balance protection of the public, health, safety, and welfare with the economic impacts of implementation. (1, 7, 9, 11, 32, 33, 39, 40, 42, 43, 45-50, 53-55, 58, 70, 71, 74-79, 89, 102, 115, 125, 157, 160, 162, 174-182, 184-1049, 3132-3560)

Response: According to the rule, initial compliance monitoring for systems serving a population of greater than 350 persons begins January 1, 2024; initial monitoring for systems serving a population of less than or equal to 350 persons begins January 1, 2025. While mandatory sampling under the rule may not require systems to begin sampling until 2024 or 2025, the MCLs will be effective upon publication of the final rule, expected in early 2023. Water systems may begin to sample for PFAS voluntarily at any point. Additionally, with the publishing of EPA's Fifth Unregulated Contaminant Monitoring Rule (UCMR5), water systems may be required to sample for contaminants identified in UCMR5 (including 29 PFAS compounds) as soon as January 2023 as determined by EPA's schedule (US EPA, 2021c). More information on UCMR5 can be found at: https://www.epa.gov/dwucmr/fifth-unregulated-contaminant-monitoring-rule.

The 2024 and 2025 initial compliance monitoring dates were selected to provide adequate time for water systems to plan for additional sampling that will be required at each entry point. Since the rule is not expected to be published as final until early 2023, water systems will have finalized their budgets for 2023 before the rule becomes final. This additional time from establishing an MCL until the start of initial monitoring will allow water systems to incorporate the cost of additional sampling and analysis into their 2024 or 2025 budgets.

There are 3,785 entry points (EPs) in Pennsylvania that will be impacted by the monitoring requirements of this rule. Samples for compliance with the rule must be submitted to an

accredited laboratory. Requiring all systems to begin monitoring immediately in 2023 would overwhelm sample capacity at accredited laboratories. The short time frames required by the approved methods would not be achievable if all systems submitted samples for analysis at the same time. In addition, the laboratories will also bear the burden of increased sample analysis through UCMR5. The phased sampling approach in the rule, which requires larger water systems to begin monitoring earlier, focuses on analyzing the drinking water of as many consumers as possible earlier in rule implementation.

In addition to laboratory considerations, a delay in initial monitoring until January 2024 will provide adequate time for water system personnel to learn the rule and train personnel. PFAS sample collection requires strict adherence to the method and trained samplers. The Department intends to conduct training in 2023 on rule implementation and sample collection techniques.

14. **Comment:** IRRC noted that legislators and many commentators assert that for systems with detections over the MCL, monthly monitoring should be required until levels are reduced below the MCL. Many commentators also support a more robust ongoing monitoring schedule than required by the proposed rule and stated that all water systems should conduct regular annual monitoring for PFAS. IRRC questioned whether a shorter monitoring timeframe following a detection was considered. IRRC requested that the Board explain how the frequency of monitoring required in the final regulation is reasonable and protects public health, safety, and welfare. (1, 7, 9, 11, 39, 42-45, 47, 48, 50-55, 61, 67, 70, 73, 76-78, 84, 89, 93, 100, 102, 112, 115, 117, 124, 125, 129, 130, 132, 141, 143, 145, 147, 160, 162, 174-179, 181, 182, 184-559, 561-1079, 1087-1089, 1091-1106, 1108-1121, 1123-2125, 3132-3560)

    Response: In the existing 40 CFR Part 141 National Primary Drinking Water Regulations and 25 Pa. Code Chapter 109 Safe Drinking Water regulations, there is a cohesive strategy for setting monitoring frequencies. For a specific contaminant, the monitoring frequency is set according to whether the contaminant is expected to cause potential adverse health effects from short-term acute exposure or long-term chronic exposure at concentrations likely to be detected in drinking water.

    The group of contaminants likely to cause acute health effects includes pathogens – such as viruses, bacteria, and protozoa – which are monitored via proxies or treatment techniques at frequencies ranging from continuously to monthly. Nitrate and nitrite are also in the acute group, but the most frequent routine monitoring required is quarterly. Short-term exposure to contaminants in the acute group can cause adverse health effects over a short duration (hours or days).

    The group of contaminants likely to cause chronic health effects is composed of everything else: volatile synthetic organic chemicals (VOCs), synthetic organic chemicals (SOCs), inorganic chemicals (IOCs), disinfection byproducts (DBPs), radionuclides, and lead and copper. Contaminants in the chronic group are monitored for compliance according to a schedule based on EPA's Standardized Monitoring Framework (SMF), with monitoring occurring quarterly or less frequently, based on previous results and whether treatment is installed for a particular contaminant (US EPA, 2020). Contaminants in the chronic group can impact health if consumed over a long duration (many years). The rulemaking adds two PFAS, PFOA and PFOS, which

are chronic contaminants. Consistent with the EPA's SMF for chronic contaminants, the rulemaking does not require monthly compliance monitoring of PFOA and PFOS.

Chronic contaminants are not monitored at transient noncommunity water systems (TNCWS), such as restaurants, because public consumption of water at such facilities is only for the short term (US EPA, 1987). For community water systems (CWS) and nontransient noncommunity water systems (NTNCWS), the PFAS monitoring framework in the rule originated in existing monitoring requirements for the organic contaminants that already have maximum contaminant levels (MCLs), namely, the VOCs and SOCs.

Initial monitoring for VOCs, SOCs, and PFAS is based on EPA's SMF and consists of four consecutive quarterly samples. The SMF monitoring frameworks for VOCs and SOCs were written to include routes for this initial monitoring to be reduced in frequency or completely waived, respectively, depending on water system and entry point (EP) characteristics. The rule includes no such initial monitoring frequency reduction or waiver options for PFAS initial monitoring, which is more protective than the SMF monitoring frameworks for VOCs and SOCs (see the Department's response to Comment #15 for additional details on PFAS monitoring waivers). At every CWS and NTNCWS EP, four consecutive quarterly samples will be required for initial compliance monitoring. The quarterly initial monitoring period will produce results that are representative of each calendar quarter, thereby representing any seasonal variations that could potentially occur.

If PFOA and PFOS are not detected during the initial quarterly monitoring period at or higher than the minimum reporting level (MRL) of 5 ppt, then the monitoring frequency would be reduced to once in every three-year compliance period. This is the same as the existing monitoring frequency reduction schedule in use for SOCs. If PFOA and PFOS are not detected at specific EPs in any of the four quarters of initial monitoring in 2024 or 2025, there is an expectation that PFOA and PFOS will not later be introduced at these EPs. While PFOA and PFOS are mobile and persistent after being introduced to the environment, this does not mean that PFOA and PFOS will spread in detectable concentrations to all public water system (PWS) source waters that are an arbitrary distance from a point of introduction. While Pennsylvania clearly has some drinking water sources vulnerable to PFOA and PFOS contamination, there are other sources, which are primarily in more rural parts of the Commonwealth, supplied by heavily forested watersheds and located far from potential sources of PFAS contamination (PSOCs) where there are no apparent pathways for introducing PFAS such that they would be detectable in a water sample. During the implementation of the Department's PFAS Sampling Plan, the Department sampled at 40 EPs supplied by baseline sources, which are located in a watershed with at least 75% forested land and at least five miles from a PSOC. Examples include intakes sited at relatively high elevations surrounded by an isolated forest watershed accessed by very low traffic service roads where the likeliest route for exposure to PFAS would be atmospheric. Only two of the 40 baseline EPs sampled (5%) had results showing detections of PFOA or PFOS, and only one (2.5%) had a detection above the MRL threshold of 5 ng/L (PA DEP, 2021c). These EPs of PWS located in relatively remote and forested watersheds will most likely be the ones with no detections during initial monitoring where monitoring will reduce immediately from the initial quarterly to three-year monitoring.

If PFOA or PFOS or both are detected during initial compliance monitoring at a level greater than or equal to the MRL but less than or equal to their respective MCLs, then the compliance monitoring frequency will remain at quarterly for the detected PFAS. If this level of detection occurs at a later time when the monitoring frequency has already been reduced to annual or every three years, then the compliance monitoring frequency will increase to quarterly. In the rulemaking, quarterly compliance monitoring continues unless both PFOA and PFOS are reliably and consistently below the MCL for at least four consecutive quarters, after which the Department may decrease the monitoring frequency to annually. Requiring four consecutive quarters with monitoring results reliably and consistently below the MCL allows the Department to evaluate how steady or variable concentrations are through at least one full seasonal cycle. "Reliably and consistently below the MCL" is defined in the rulemaking for PFAS as "less than 80% of the MCL" for each sample result. Annual compliance monitoring continues in perpetuity until there is a reversion to quarterly monitoring after a detection as described above, or until a waiver is granted (see the Department's response to Comment #15 for a description of the considerations for granting PFAS monitoring waivers); this matches the current monitoring frameworks for VOCs and SOCs.

If PFOA or PFOS or both are detected at a level greater than their respective MCL, the monitoring response is the same as when one or both chemicals are detected between the MRL and MCL as described above: compliance monitoring is required quarterly. The only difference here is that compliance with the MCL must also be considered in accordance with 25 Pa. Code § 109.301(16)(ix). When sample results indicate a violation of one or both MCLs, follow-up actions are required, including one-hour notification to the Department, consultation with the Department on appropriate corrective actions, and Tier 2 public notification (PN) (see the Department's response to Comment #16 for more information on actions following a PFAS MCL exceedance or violation). Once an MCL violation occurs and a PWS issues Tier 2 PN and begins taking corrective actions to comply with one or both MCLs, there is no significant health or information benefit obtained from conducting compliance monitoring for these chronic contaminants at the entry point more frequently than quarterly.

When treatment for PFOA or PFOS is in place, the rule requires that the performance efficacy of the treatment is demonstrated through performance monitoring, conducted on a frequency of at least quarterly in perpetuity, according to 25 Pa. Code § 109.301(16)(vi). Performance monitoring frequency and locations are generally specified by permit special conditions to demonstrate treatment efficacy. The performance monitoring frequency and locations are specific to the treatment techniques to ensure the treatment is achieving the performance goals.

For bottled water, vended water, retail water, and bulk water systems (BVRBs), the PFAS monitoring framework originated in those existing for the organic contaminants that already have MCLs, namely, the VOCs and SOCs. For BVRBs there are a few notable differences from the compliance monitoring described above for the other types of systems. BVRBs that obtain finished water from another public water system are exempt from monitoring as long as the supplying system monitors at least annually. A typical example of this is a vended water system at a grocery store that adds treatment beyond compliance level to already consumable water supplied by a CWS. Another difference is that BVRB monitoring cannot be any less frequent than annual.

It is possible PFOA or PFOS could be newly introduced to the surface water or groundwater supplying a PWS at a level that would cause an EP detection above the MRL or respective MCL. If the Department becomes aware of such contamination, the Department may require special monitoring in addition to the initial and repeat compliance monitoring described above, in accordance with 25 Pa. Code § 109.302(a)-(b) and § 109.1003(i). That is, if there is reason to believe there is new PFOA or PFOS contamination, the Department may require a system to sample more frequently than its current compliance monitoring frequency.

The EPA made a final determination to regulate PFOA and PFOS at the federal level, and though a proposed federal regulation has not been published, there are indications about what the federal compliance requirements will be (US EPA, 2021). EPA is considering two monitoring approaches. First, EPA is considering using the SMF for SOCs, under which compliance monitoring schedules are based around the detection levels of the regulated contaminants, and state primacy agencies can also issue waivers for monitoring. The SMF does not require compliance monitoring more frequently than quarterly (US EPA, 2020). Second, an alternative monitoring approach would allow state primacy agencies to require monitoring at PWSs where information indicates potential PFAS contamination, such as proximity to facilities with historical or ongoing uses of PFAS. There is thus no expectation that the final federal rule will require monitoring to be more frequent than quarterly. Note that the EPA states "As the Agency promulgates the regulatory standard for PFOA and PFOS, EPA will continue to work to establish monitoring requirements in the rule that minimize burden while ensuring public health protection" (US EPA, 2021).

15. **Comment:** IRRC noted that legislators and many commentators urge the Board to amend the rulemaking to require all water systems to be monitored on at least an annual basis with no waivers being granted. IRRC requested that the Board explain how it determined that the granting of waivers will not negate the protection of the public health, safety, and welfare afforded by consistent testing. (1, 7, 9, 11, 39, 42-45, 47, 48, 50-55, 61, 67, 70, 73, 76-78, 84, 89, 93, 100, 102, 112, 115, 117, 124, 125, 129, 130, 132, 141, 143, 145, 147, 160, 162, 174-179, 181, 182, 184-559, 561-1079, 1087-1089, 1091-1106, 1108-1121, 1123-2125, 3132-3560)

Response: The Board determined that the granting of waivers only under very specific conditions would decrease industry costs while continuing to protect the public health, safety, and welfare. For CWS and NTNCWS, the PFAS waiver framework follows the existing waiver framework for VOCs. The ability to waive monitoring for VOCs is significantly more limited than that for SOCs. Important conditions on waivers for PFAS in the rulemaking that should be considered include the following:

- Under the rule, a PWS can only apply for a waiver after the PWS completes three consecutive years of quarterly or annual samples with no detection of PFOA or PFOS. This would only be done after an earlier detection because EPs that have never had a detection would move directly to monitoring every three years without needing a waiver application.

- The waiver does not allow a complete stop to monitoring as can occur with SOCs. With a waiver, PFAS compliance monitoring is still conducted once every three years at a minimum.

- Waivers are only available at EPs supplied by groundwater or groundwater under the direct influence of surface water (GUDI). EPs supplied by surface water will not be eligible for waivers because many CWS and NTNCWS do not have complete control over their surface water intake protection area (defined in 25 Pa. Code § 109.1).

- Waivers are only available after evaluating land use and the use of PFAS in wellhead protection area Zone II (defined in § 109.1). This includes consideration of storage, manufacturing, transport, and/or disposal.

- Granting waivers is at the Department's discretion. There is no guarantee that the Department will grant waivers for every application submitted. For example, it is reasonable that the Department may deny a waiver application for an EP with a previous MCL exceedance where the cause of the MCL exceedance is unknown.

- A waiver will not be granted for PFOS if there is treatment for PFOA and vice-versa.

The waiver process is a balance between requiring monitoring protective of public health and allowing a reduction in monitoring when a PFAS has an isolated appearance, has exited the system, decreases below the minimum reporting level, and there is no known use of it near the groundwater source. That is, monitoring is only reduced when there is no expectation a PFAS detection will recur. As listed above, there are a number of conditions that have to be met for a waiver to be granted, and the granting of waivers will not negate the protection of public health.

Waivers are not available for BVRBs, but there is a possible exemption from monitoring as described above for BVRBs supplied with finished water from another system.

See the Department's response to Comment #14 for an explanation of how monitoring frequencies were determined.

16. Comment: IRRC questioned whether a water system could remain in the state of repeat monitoring and never reach compliance following an MCL exceedance. Numerous commentators asserted that the Department should implement methods to decrease contamination if levels are above the MCLs for two consecutive quarters. IRRC requested that the Board explain how it will ensure that compliance is achieved by water systems. (1, 28, 39, 44, 53, 55, 63, 73, 82, 1050-1079, 1103)

Response: Following an MCL exceedance, the Department will follow established procedures for ensuring the water system does not simply remain in the state of repeat monitoring, but ultimately reaches compliance, as described in this response. The rulemaking establishes MCLs for two PFAS: PFOA at 14 ppt and PFOS at 18 ppt. MCL compliance will be determined in accordance with 25 Pa. Code § 109.301(16)(ix) and will be based on a Running Annual Average (RAA) calculated quarterly as is the case with other currently regulated chronic contaminants,

including volatile synthetic organic chemicals (VOCs), inorganic chemicals (IOCs), synthetic organic chemicals (SOCs), and Disinfection Byproducts (DBPs).

Under existing authorities in § 109.701(a)(3)(i), public water systems (PWSs) are required to notify the Department within one hour if any single sample result exceeds an MCL value or if the system is determined to be in violation of an MCL, according to § 109.301(16)(ix) for PFOA and PFOS. An initial consultation with the Department typically occurs during this notification regarding any immediate actions. When a PWS is in violation of an MCL, the Department issues a Notice of Violation (NOV), according to the Department's technical guidance document, *Guidelines for Identifying, Tracking and Resolving Violations for the Drinking Water Program* (383-4000-002). According to that guidance document, the NOV contains requested actions and associated timeframes, including a request for the PWS to consult with the Department to determine appropriate corrective actions (PA DEP, 2006a). In addition to issuing public notification, corrective actions may include additional monitoring, installation of treatment, using alternative sources, blending sources, or taking a source offline. PWSs are responsible for taking any and all corrective actions necessary to protect public health.

When systems fail to take corrective action and continue to be in violation of an MCL, the Department identifies the ongoing MCL violation as a significant deficiency which is defined in § 109.1 as "A defect in design, operation or maintenance, or a failure or malfunction of the sources, treatment, storage or distribution system that the Department determines to be causing, or has the potential for causing the introduction of contamination into the water delivered to consumers." The Department notifies the PWS of the ongoing MCL violation and the identification of the ongoing violation as a significant deficiency through an NOV. This NOV outlines the regulatory responsibilities of systems as stipulated in existing § 109.717 for responding to significant deficiencies. These responsibilities are:

(1) Within 30 days of receiving written notification, the public water supplier shall consult with the Department regarding appropriate corrective actions unless the Department directs the system to implement a specific corrective action.

(2) The public water supplier shall respond in writing to significant deficiencies no later than 45 days after receipt of written notification from the Department, indicating how and on what schedule the system will address significant deficiencies.

(3) Corrective actions shall be completed in accordance with applicable Department plan review processes or other Department guidance or direction, if any, including Department-specified interim measures.

(4) The public water supplier shall correct significant deficiencies identified within 120 days of receiving written notification from the Department, or earlier if directed by the Department, or according to the schedule approved by the Department.

The exact corrective actions in response to an MCL violation are not codified in regulation because they are case specific and may vary based on each individual situation and system

specific considerations, including the level detected, any known or suspected source of contamination, other water sources available, and treatment processes already in place. Sufficient quarterly monitoring data may be necessary to evaluate whether there are seasonal variations in contaminant levels in order to identify the most appropriate corrective actions. The corrective action process required for significant deficiencies ensures the corrective actions occur within 120 days or upon an alternative schedule approved by the Department. As MCL corrective actions are almost always subject to the permitting process, the Department often enters into a Consent Order and Agreement with the system to formally extend the 120 due date while establishing other enforceable deadlines.

Public notification, when required, shall be delivered to the customers consistent with existing regulations.

17. **Comment:** IRRC noted that proposed § 109.301(16)(ii)(B) in the proposed rulemaking included the phrase "reliably and consistently below all MCLs for PFAS," which is inconsistent with the term defined in Section 109.1, "reliably and consistently below the MCL." EPA Region 3 noted that Section F of the preamble to the proposed rulemaking did not address the definition of "reliably and consistently below the MCLs" relevant to reduced frequency of repeat monitoring. IRRC requested that the Board amend the rulemaking to clarify this inconsistency. (1, 12)

    Response: The monitoring requirements in § 109.301 and § 109.1003 have been revised in the final-form rulemaking so that the required monitoring frequencies for PFOA and PFOS are determined independently. In conjunction with this, all instances of "reliably and consistently below all PFAS MCLs" have been revised to "reliably and consistently below the MCL," which is consistent with § 109.1. As EPA noted, this was not specifically defined in the preamble to the proposed rulemaking, but the existing definition in § 109.1 is edited in the rulemaking to include PFAS. As defined in § 109.1, "reliably and consistently below the MCL" indicates that "For VOC, SOCs, IOCs (with the exception of nitrate and nitrite), and PFAS, this means that each sample result is less than 80% of the MCL."

18. **Comment:** IRRC and a commentator noted that proposed § 109.301(16)(viii)(A) states "The Department may invalidate results of obvious sampling errors." IRRC questioned what the standards are for determining an "obvious" sampling error and how samples will be evaluated consistently. IRRC requested that the Board clarify implementation related to the invalidation of PFAS samples. (1, 18)

    Response: The language used in § 109.301(16)(viii) matches that already in use for the other groups of regulated organic chemicals, the volatile synthetic organic chemicals (VOCs) and synthetic organic chemicals (SOCs). As specified in § 109.304(f)(1), "Sampling and analysis shall be according to the following approved methods" which include EPA Method 533, EPA Method 537.1, or EPA Method 537 Version 1.1. Failure to follow the "Sample Collection, Preservation, and Storage" steps in the chosen method could result in sample invalidation. Decisions about sample invalidations will be based on available documentation. For example, if a sample is taken at a tap other than the entry point, that error would have to be determinable from documentation.

If PFOA or PFOS is detected in a field reagent blank (FRB) sample, it could be considered an obvious sampling error, if there is evidence that indicates PFOA or PFOS was introduced by the sampler. Alternatively, PFOA or PFOS could have a long-term presence in the area surrounding the sample tap for other reasons. According to the approved methods, the consequence of a substantial FRB detection is the same regardless of the reason for it:

- EPA 533: "If a method analyte found in the field sample is present in the FRB at a concentration greater than one-third of the MRL [minimum reporting level], then the results for that analyte are invalid for all samples associated with the failed FRB." (Rosenblum, 2019)

- EPA 537.1 and EPA 537 Version 1.1: "If the method analyte(s) found in the Field Sample is present in the FRB at a concentration greater than 1/3 the MRL, then all samples collected with that FRB are invalid and must be recollected and reanalyzed." (Shoemaker, 2009; Shoemaker, 2018)

Obvious sampling errors will be further addressed in guidance materials and in training, which will be provided by the Department after the final rule is promulgated.

19. Comment: IRRC and some commentators noted the compliance determination in proposed § 109.301(16)(ix)(A). IRRC requested that the Board clarify how the compliance determination will be implemented for systems that choose to monitor more frequently than required. Specifically, a few commentators requested clarification on the compliance determination for a system that is required to monitor quarterly but instead monitors monthly. (1, 13, 29)

Response: The clauses that specify how compliance determinations are dependent on monitoring frequency are:

- § 109.301(16)(ix)(A): "For systems monitoring more than once per year, compliance with the MCL is determined by a running annual average of all samples taken at each entry point." The running annual average (RAA), as defined in 109.1, is the "average, computed quarterly, of quarterly arithmetic averages of all analytical results for samples taken during the most recent 4 calendar quarters." Therefore, individual monthly results will not be used directly for compliance; instead, the monthly results will be averaged within each calendar quarter to calculate a quarterly average, and then compliance is determined using that quarterly average.

- § 109.301(16)(ix)(B): "If monitoring is conducted annually or less frequently, the system is out of compliance if the level of a contaminant at any entry point is greater than the MCL. If a confirmation sample is collected as specified in subparagraph (v), compliance is determined using the average of the two sample results." Note that subparagraph (v) states, "A confirmation sample shall be collected and analyzed for each of the PFAS detected in exceedance of its MCL during annual or less frequent compliance monitoring." Confirmation samples should only be collected during annual or less frequent monitoring.

Compliance is determined based on the monitoring frequency in use and not on the monitoring frequency required. For example, if a system required to monitor annually is monitoring quarterly, an RAA will be calculated to determine compliance, as described in § 109.301(16)(ix)(A). As another example, if a system required to monitor quarterly is monitoring monthly, a quarterly average will be calculated with the monthly results each quarter and those quarterly averages will be used to calculate compliance according to § 109.301(16)(ix)(A).

20. Comment: IRRC and some commentators noted the compliance determination for quarterly monitoring in proposed § 109.301(16)(ix)(C) and requested clarification on implementation. Specifically, IRRC and commentators requested clarification on whether a determination of "out of compliance" will begin with the first sampling following the effective date of the regulation, and whether a system will be out of compliance if the first sample exceeds the MCL. (1, 13, 29)

Response: A system is not necessarily out of compliance if the first sample exceeds the MCL. In accordance with § 109.301(16)(ix)(A), during the initial year of quarterly compliance monitoring, compliance with each MCL will be determined by a running annual average (RAA) of all sample results for each of the regulated PFAS. The RAA, as defined in § 109.1, is the "average, computed quarterly, of quarterly arithmetic averages of all analytical results for samples taken during the most recent 4 calendar quarters." Note that the four calendar quarters are Q1 (January–March), Q2 (April–June), Q3 (July–September), and Q4 (October–December).

During the first year of monitoring, results will not exist for all four of the most recent calendar quarters until the result from Q4 is available. Until that point, results for quarters that have not yet occurred are assumed to be less than the minimum reporting level (MRL) and, thus, are entered as zero in the RAA calculation in accordance with § 109.301(16)(ix)(E). Therefore, for example, if a system is required to test in March 2024 (Q1) for the first time, the following three quarters (Q2 2024, Q3 2024, and Q4 2024) will be entered as zero.

Consider a PWS beginning initial PFAS compliance monitoring in Q1 2024. The concentration of a specific PFAS in the n^{th} quarter of year yyyy is labeled *C*(Qn yyyy). As noted in the Department's response to Comment #19, if more than one sample is reported in a quarter, *C*(Qn yyyy) represents a quarterly average of all reported results. The concentrations for each quarter to be used in the RAA calculation would then be signified as follows:

Q1 2024	Q2 2024	Q3 2024	Q4 2024
C(Q1 2024)	*C*(Q2 2024)	*C*(Q3 2024)	*C*(Q4 2024)

In this scenario, the following table shows how the RAA will be determined during each quarter of 2024:

Most Recent Quarter	RAA
Q1 2024	*C*(Q1 2024) / 4
Q2 2024	(*C*(Q1 2024) + *C*(Q2 2024)) / 4
Q3 2024	(*C*(Q1 2024) + *C*(Q2 2024) + *C*(Q3 2024)) / 4
Q4 2024	(*C*(Q1 2024) + *C*(Q2 2024) + *C*(Q3 2024) + *C*(Q4 2024)) / 4

If a system fails to collect a sample in all quarters of the initial year of compliance monitoring, then, in accordance with § 109.301(16)(ix)(D), compliance with the MCL will be based on the total number of quarters in which results were reported. As an example from the above scenario, if the Q2 2024 sample is missed, but all others are taken, then the RAA calculations for the initial year of compliance monitoring would be:

Most Recent Quarter	RAA
Q1 2024	*C*(Q1 2024) / 4
Q2 2024	*C*(Q1 2024) / 4
Q3 2024	(*C*(Q1 2024) + *C*(Q3 2024)) / 4
Q4 2024	(*C*(Q1 2024) + *C*(Q3 2024) + *C*(Q4 2024)) / 3

Note that in subsequent years of quarterly compliance monitoring, the Q4 2024 RAA calculation would apply for years in which quarterly results do not exist for one quarter. In other words, using the RAA calculation, compliance will still be based on the total number of quarters in which sample results were reported.

Using the compliance calculations explained above, compliance will be calculated beginning with the first quarterly result of initial monitoring. According to § 109.301(16)(ix)(C), "If any sample result will cause the running annual average to exceed the MCL at any entry point, the system is out of compliance with the MCL immediately." In other words, if at any point a quarterly sample result yields an MCL exceedance using the compliance calculations described above, the system is out of compliance. For example, if the first quarterly result of initial compliance monitoring is more than four times the MCL, the system is out of compliance based on the compliance calculation for the first quarter of initial quarterly monitoring. However, if the first quarterly result is at a level that is over the MCL but not over four times the MCL, the system would not be out of compliance.

21. Comment: IRRC and a commentator noted the requirement in proposed § 109.301(a)(6)(ii), "Samples shall be collected by a person properly trained by a laboratory accredited by the Department to conduct PFAS analysis." One commentator requested clarification of this provision and noted several limitations to its implementation. IRRC requested that the Board amend the final rule to address commentators' concerns, including laboratory staff capacity, geographic availability, economic impacts of associated costs and training costs, and certification or documentation needed to verify training. (1, 18)

Response: In response to these comments, subparagraph § 109.303(a)(6)(ii) has been removed from the final-form rulemaking. This will instead be addressed in guidance materials and in training, which will be provided by the Department after the final rule is adopted.

22. **Comment:** IRRC and a commentator noted the analytical requirements included in the proposed rulemaking and questioned whether those requirements should be removed from the rulemaking and instead included in guidance or codified in the Department's Environmental Laboratory Accreditation regulations at 25 Pa. Code Chapter 252. IRRC requested that the Board explain the need for and reasonableness of retaining analytical requirements in the final regulation. (1, 18)

    Response: The existing analytical requirements have been established through § 109.304(a), which states "Sampling and analysis shall be performed in accordance with analytical techniques adopted by the EPA under the Federal act or methods approved by the Department." The analytical techniques adopted by the EPA under the Federal act are specified explicitly in the National Primary Drinking Water Regulations in 40 CFR Part 141 Subpart C - Monitoring and Analytical Requirements. The EPA has not yet adopted analytical techniques for PFAS in 40 CFR Part 141 Subpart C. Therefore, in accordance with § 109.304(a), the Department is responsible for approving methods for PFAS analysis. Updating 25 Pa. Code Chapter 252 would require a procedure equivalent to updating Chapter 109, so there would be no flexibility gained from listing the methods in Chapter 252 instead. By explicitly specifying these methods in § 109.304(f), the Department is following the EPA's convention.

23. **Comment:** IRRC and a commentator noted the list of approved treatment technologies for achieving compliance with the proposed PFAS MCLs included in proposed § 109.602(j)(1) and questioned whether a PWS would be able to move forward without piloting for one of the listed technologies, or whether pilot testing will be required prior to issuance of a construction permit. One commentator noted the additional cost of pilot testing and the availability of existing data for evaluation of performance. IRRC requested that the Board clarify whether piloting will be required for the approved treatment technologies listed in the proposed rulemaking, and, if so, to amend the final regulation and associated documents to take the additional costs and economic impacts into consideration. (1, 28)

    Response: The Department currently is not requiring PWSs to pilot all PFAS treatment projects. However, the Department retains the right to require piloting even if the technology is listed as approved in regulation, as the Department can for all types of treatment processes.

    Piloting provides real-world data that will allow for accurate sizing and operational cost of the treatment system that can be an overall net saving. A pilot study provides a site-specific basis for the development of loading rates, operational costs, and which technology or equipment manufacture is best suited for the project. Additionally, having the piloting data minimizes the overall risk to the project. Piloting costs vary depending on the length of the pilot, number of technologies tested, and the specifics of the raw water quality. There are multiple water quality parameters that can affect the sizing, cost, and operation of the treatment. Piloting costs generally are less than 5% of the total cost of the project.

The Department encourages piloting for the technology listed as approved for PFAS treatment to develop site-specific design requirements. For systems that have provided successful demonstration of a technology on similar water quality, the Department has not required a pilot study. The PWS is responsible for demonstrating similarity in water quality to the Department.

24. Comment: IRRC noted proposed § 109.602(j)(2), which states "Other treatment technologies may be approved by the Department if the applicant demonstrates the alternate technology is capable of providing an adequate and reliable quantity and quality of water to the public." IRRC questioned what standards would determine adequacy has been demonstrated and requested that the Board clarify how this provision will be implemented. (1)

Response: This provision will be implemented in the same manner in which it would be for any other contaminant or any innovative treatment technology; it is addressed in Section I.C. of the Department's *Public Water Supply Manual Part II, Community System Design Standards* (383-2125-108), which states:

> "The risk incurred in experimentation with innovative treatment processes must rest upon the proponent of the method rather than the public. Recent developments or new equipment may be acceptable if they meet at least one of the following conditions:
>
> - The treatment process has been thoroughly tested in full-scale comparable installations under competent supervision.
>
> - The treatment process has been thoroughly tested in a pilot plant operation for a sufficient time to ensure the technology provides drinking water which meets DEP's drinking water standards under all conditions of raw water quality." (PA DEP, 2006b)

25. Comment: Legislators and numerous commentators stated that Pennsylvania should develop MCLs for more PFAS chemicals, in addition to the proposed levels of 14 ppt for PFOA and 18 ppt for PFOS in the proposed rulemaking or questioned whether the Department will address other PFAS. Some commentators asserted that all PFAS found in Pennsylvania should have MCLs; some commentators specifically mentioned including PFNA, PFHxA, PFHxS, PFHpA, and PFBS; and some commentators suggested including the 18 PFAS listed in EPA Method 537.1 in the rulemaking. One commentator who expressed support for the proposed rulemaking also urged the Department to "continue to examine other PFAS chemicals, which similarly have been shown to cause negative health impacts. This could include chemicals such as perfluorobutyrate (PFBA) and perfluorohexanoic acid (PFHxA)." (4, 5, 9, 11, 17, 31-33, 35-37, 39, 40, 42, 43, 45, 47-55, 58, 61, 62, 69, 70, 73-75, 77, 78, 81, 84, 87, 89, 92, 93, 102, 106, 109, 112, 113, 115, 117, 119, 124, 126-130, 132, 139, 141, 143, 145, 147, 148, 157, 160, 162, 164, 174-182, 184-1049, 1054-1114, 1116-1121, 1123-2125, 2777-2794, 2976-3560)

Response: As explained in the preamble to the proposed rulemaking, the Department must follow a rigorous process when setting an MCL. An MCL rulemaking must be based on available data, studies, and science, and must consider all factors as required by the Federal Safe Drinking Water Act (Federal Act) (42 U.S.C.A. §§ 300f—300j-27) and the Commonwealth's

Regulatory Review Act (RRA) (71 P.S. §§ 745.1—745.14). Among other things, the Department must consider health effects, occurrence data, technical limitations such as available analytical methods and detection and reporting limits, treatability of the contaminant and available treatment technologies, and costs and benefits (71 P.S. § 745.5b) (EQB, 2022).

In addition to State requirements, the Department needs to consult the Federal Act and its implementing regulations. See 42 U.S.C.A. §§ 300f—300j-9; see also 40 CFR Parts 141, 142, and 143 (relating to National Primary Drinking Water Regulations; National Primary Drinking Water Regulations Implementation; and other Safe Drinking Water Act Regulations). The EPA explains how EPA sets standards at the following link: www.epa.gov/sdwa/how-epa-regulates-drinking-water-contaminants. In establishing the MCLs in this rulemaking, the Department was informed by the EPA's procedure to establish an MCL. It is important for the Department to understand the EPA's process of setting an MCL because similar criteria are required of the Department under the Commonwealth's RRA and because the MCLs in this rulemaking are the first MCLs that the Department has set; every other MCL in effect in this Commonwealth was set by the EPA and incorporated by reference into the Department's Chapter 109 regulations. In addition, to retain primacy for implementing the Federal Act in this Commonwealth, the Department's standard setting process must be at least as stringent as the Federal process.

Once an MCLG is determined, the EPA sets an enforceable standard. In most cases, the standard is an MCL. The MCL is set as close to the MCLG as feasible. Taking cost into consideration, the EPA must determine the feasible MCL. As a part of the rule analysis, the Federal Act requires the EPA to prepare a health risk reduction and cost analysis in support of any standard. The EPA must analyze the quantifiable and nonquantifiable benefits that are likely to occur as the result of compliance with the proposed standard. The EPA must also analyze increased costs that will result from the proposed drinking water standard. In addition, the EPA must consider incremental costs and benefits associated with the proposed alternative MCL values. Where the benefits of a new MCL do not justify the costs, the EPA may adjust the MCL to a level that maximizes health risk reduction benefits at a cost that is justified by the benefits.

In 2019, the Department's Safe Drinking Water Program moved forward with its PFAS Sampling Plan, which was a key project to advance the program's knowledge of PFAS, specifically occurrence of PFAS in public water systems (PWSs) this Commonwealth. In the preamble to the proposed rule, Table 1. *Summary of PFAS Sampling Plan results* provides a summary of the results from the PFAS Sampling Plan; full results are available at www.dep.pa.gov/pfas (EQB, 2022). Of the 412 samples analyzed for PFOA, 112 (27%) resulted in detectable concentrations of PFOA; the remaining 300 samples resulted in no detectable concentrations of PFOA. Of the 412 samples analyzed, 103 samples (25%) resulted in detectable concentrations of PFOS; the other 309 resulted in no detectable concentrations of PFOS. At the sampling sites with detections, eight of the 18 PFAS included in EPA Method 537.1 were detected. The eight PFAS that were detected are: PFOA, PFOS, PFNA, PFHxS, PFHpA, PFBS, PFHxA, and perfluoroundecanoic acid (PFUnA). Of the eight PFAS detected, PFOA and PFOS were most common, detected at 112 (or 27%) and 103 (or 25%) sites, respectively. Results were non-detect at all 412 sites for the other ten PFAS that were analyzed (PA DEP, 2021c).

The Department is proposing not to move forward with an MCL for other PFAS at this time for multiple reasons, including the lack of occurrence data above the MCLG for other PFAS, incomplete cost/benefit data and analysis, reference dose not derived due to lack of evidence on toxicity, and lack of treatability data. For specific reasons by contaminant, refer to the preamble to the proposed rulemaking, Table 4**.** *Reasons for not moving forward with MCLs for other PFAS* (EQB, 2022).

In Table 4 in the preamble to the proposed rulemaking, the phrase "lack of occurrence data above the MCLG" was intended to mean "lack of *sufficient* occurrence data above the MCLG", not necessarily that the Department found *no* detections exceeding the recommended MCLG for a particular compound in the PFAS Sampling Plan results. The Department acknowledges that there was a small percentage of detections of PFBS, PFHpA, PFHxS, and PFNA in the occurrence data. However, the infrequency of detection of those PFAS compounds is small enough to not be indicative of a substantial likelihood that any of them will occur in PWSs at levels and frequencies of public health concern. The data do not suggest a meaningful opportunity to regulate other PFAS compounds besides PFOA and PFOS.

The decision to not move forward with MCLs for additional PFAS at this time is further supported by a review of co-occurrence data. This review considers the frequency with which individual PFAS detections co-occurred with other PFAS detections in the occurrence data set used for this rulemaking. PFAS are a large class of man-made synthetic chemicals, and because of their unique chemical structure, the treatment for PFOA and PFOS is the same, as is treatment for many other PFAS found in water sources. If MCLs for PFOA and PFOS are exceeded and treatment is the recommended option, this treatment would be PFAS removal treatment. Based on an analysis of co-occurrence data, only 3.7% of all sites (or 16 out of 435 sites) had detections of at least one other PFAS at a level greater than its recommended MCLG when PFOA or PFOS levels did not exceed the MCLs (PA DEP, 2021c). In other words, the PFOA and PFOS MCLs appear to be protective of other PFAS in up to 96.3% of PWSs with detectable concentrations of other PFAS. Therefore, PFAS removal treatment installed for PFOA and PFOS exceedances is expected to provide some protection against other PFAS contaminants in up to 96.3% of PWSs with treatment installed for PFOA or PFOS or both.

It is important to note that the PFAS Sampling Plan was a targeted sampling plan, with the intent of prioritizing PWS sources potentially affected by PFAS contamination to be sampled. Of the 412 sites sampled, 40 sites (approximately 10%) were located in a watershed with at least 75% forested land and at least five miles from a potential source of PFAS contamination (PSOC). These 40 sites served as a control group. The remaining 372 sites (approximately 90%) were located within 0.5 to 0.75 miles of a PSOC (PA DEP, 2019). For a full description of PSOCs identified and selection of potential sampling sites, the PFAS Sampling Plan is available at https://files.dep.state.pa.us/Water/DrinkingWater/Perfluorinated%20Chemicals/BSDW%20PFAS%20Sampling%20Plan_Phase%201_April%202019.pdf. Because the sampling plan was predominantly targeted to PWS sources located in proximity to PSOC, the detection rates from the occurrence data may overestimate the detection rate for other PWSs in this Commonwealth that were not sampled.

The Department acknowledges that the science on PFAS is evolving. While the most recent scientific studies and data available at the time were used in development of the rulemaking, newer studies on the toxicity and health effects of several PFAS are on the horizon. The EPA is also in ongoing consultation with the EPA's Science Advisory Board in the evaluation of additional PFAS and groups of PFAS. The Department recognizes that there will be a need to continue to reevaluate the science and data relative to PFAS. However, the Department also considers this an important opportunity to move forward with this rulemaking that will increase public health protection for Pennsylvanians served by PWS from adverse health effects associated with exposure to PFOA and PFOS in drinking water.

26. Comment: Legislators and most commentators pointed out the large number of Pennsylvanians that receive their water from private water sources including private wells. These commentators expressed their concern that this large portion of Pennsylvanians will be left unprotected by this proposed rulemaking and requested that the Department include private water sources in the requirements of the proposed rule. (7, 9, 11, 17, 32, 33, 36, 37, 39, 42-55, 61, 67, 70, 72-74, 76-78, 85, 85, 89, 92, 93, 102, 105, 107, 109, 112, 115, 117, 119, 124-130, 132, 141, 143, 145, 147, 152, 160, 162, 170, 172, 174-1079, 1087-1098, 1100-1106, 1108-1114, 1116-1121, 1123-2129, 2131-2133, 2135-2776, 3132-3560)

Response: These comments are outside the scope of this rulemaking, but the Department acknowledges them. Under Pennsylvania law, the Department does not have the authority to regulate private water sources. The Pennsylvania Safe Drinking Water Act (the Act) states that rules and regulations established by the Environmental Quality Board (Board) "shall apply to each public water system in the Commonwealth ..." (35 P.S. § 721.4(b)). The Act defines a public water system as "a system for the provision to the public of water for human consumption which has at least 15 service connections or regularly serves an average of at least 25 individuals daily at least 60 days out of the year." (35 P.S. § 721.3).

The Act grants authority for the Board to establish rules and regulations which govern only public water systems, not private water systems (which include privately owned water wells). The Act additionally grants authority to the Department to enforce only Federal and State regulations regarding well design and construction standards and drinking water standards. As Federal standards and state standards established by the Board govern only public water systems, DEP cannot enforce standards for public water systems on privately owned wells, seeps, and springs that do not meet the definition of a public water system; therefore, this comment is outside the scope of this rulemaking.

Although the Department may not enforce public water system regulations on privately owned water systems, the Department often receives questions regarding privately owned wells. Information regarding well construction, drinking water testing and treatment, and other information are available on the Department's website at https://www.dep.pa.gov/Citizens/My-Water/PrivateWells/pages/default.aspx.

27. Comment: Legislators and numerous commentators referenced Article I, Section 27 of the Pennsylvania Constitution when suggesting that MCLs for PFOA and PFOS should be set lower than proposed or at zero detection, the MCLs should apply to private water supplies, MCLs

should be set for other PFAS in addition to PFOA and PFOS, and implementation of the regulation should start immediately without phasing in the compliance monitoring. Article I, Section 27 states "The people have a right to clean air, pure water, and to the preservation of the natural, scenic, historic, and esthetic values of the environment." (5, 10, 45, 47, 49, 50, 58, 68, 70, 71, 73, 79, 113, 123, 140, 154, 164, 1105, 2133, 2791)

Response: The Pennsylvania Safe Drinking Water Act under section 2(b) has declared that the purpose of the act is to further the intent of Article I, Section 27 of the Pennsylvania Constitution by, among other things, establishing a state program to provide safe drinking water to the public. As part of that state program to provide safe drinking water to the public, this rulemaking is intended to protect public health by setting State MCLs for contaminants in drinking water that are currently unregulated at the Federal level. With these amendments to Pennsylvania's safe drinking water regulations, the Commonwealth would move ahead of the EPA in addressing PFOA and PFOS in drinking water. Safe drinking water is vital to maintaining healthy and sustainable communities. Proactively addressing PFOA and PFOS contamination in drinking water can reduce the incidence of illness and reduce health care costs.

As explained in the preamble to the proposed rulemaking, the Department must follow a rigorous process when setting an MCL. An MCL rulemaking must be based on available data, studies, and science, and must consider all factors as required by the Federal Safe Drinking Water Act (Federal Act) (42 U.S.C.A. §§ 300f—300j-27) and the Commonwealth's Regulatory Review Act (RRA) (71 P.S. §§ 745.1—745.14). Among other things, the Department must consider health effects, occurrence data, technical limitations such as available analytical methods and detection and reporting limits, treatability of the contaminant and available treatment technologies, and costs and benefits (71 P.S. § 745.5b) (EQB, 2022). See the Department's responses to Comment #11 for a description of the MCL rulemaking process, Comment #9 for a discussion of the scientific studies and data used in the rulemaking process, Comment #26 for an explanation why the rulemaking does not apply to private water supplies, Comment #25 regarding setting MCLs for PFAS other than PFOA and PFOS, and Comment #13 regarding the timing of compliance monitoring.

28. Comment: IRRC noted that a commentator states that drinking water facilities are passive entities that are subject to this regulation due to the action of others. The commentator further notes that "[m]ost, if not all, of these facilities were not designed to treat emerging contaminants such as PFAS." The commentator urges the Department to undertake regulatory initiatives that address, at a minimum, source control requirements related to PFAS to eliminate or substantially reduce, among other things, the costs of PFAS treatment, management, and monitoring that will be directly borne by the regulated community. The Board should address the impact of other regulatory initiatives related to PFAS source control requirements on the economic impacts of the final regulation. (1, 17)

Response: The Department acknowledges that PWSs are not responsible for releasing PFAS into the environment. Decades of widespread use of a wide variety of products containing PFAS has resulted in elevated levels of environmental pollution and exposure in some areas of Pennsylvania, and PFAS remain in the environment and cycle through various media (air, water, soil) depending on how and where the substances were released. Although these broader issues

are outside the scope of this particular rulemaking, it is important to note that the Department has undertaken initiatives within its statutory authorities to address PFAS contamination holistically and to minimize further releases and exposures. As part of the multi-agency PFAS Action Team established by Governor Wolf, the Department is actively exercising its statutory authorities to implement regulatory and permitting initiatives to address PFAS contamination.

In November 2021, the Board promulgated regulatory provisions in 25 Pa. Code Chapter 250 Administration of the Land Recycling Program to address PFAS contamination in soil and groundwater. The regulatory provisions established soil and groundwater Medium Specific Concentrations (MSC) for PFOS, PFOA, and PFBS under the Statewide Health Standard. Through this regulatory update, remediators must demonstrate attainment of a standard provided by the Land Recycling and Environmental Remediation Standards Act (Act 2 of 1995) and obtain Act 2 liability relief for PFOA, PFOS, and PFBS. By law, the Department is required to review these standards every 36 months to ensure the MSCs reflect the most current science available to protect human health and the environment. Once a state or federal MCL is published, it will become the updated MSC as required by Act 2.

The Department also recently established a multi-pronged strategy to better characterize and control PFAS in permitted discharges to surface waters by implementing monitoring and other requirements in National Pollutant Discharge Elimination System (NPDES) permits. The Department's PFAS strategy for NPDES discharges includes: identifying industries likely to discharge PFAS; revising NPDES permit applications for these industries and for major sewage facilities receiving discharges from these industries to include PFOA and PFOS sampling requirements and, where relevant, source evaluations; and adding monitoring requirements for PFOA and PFOS to NPDES permits from facilities with identified elevated concentrations in their effluent and, where necessary, evaluating the need for effluent limits for those facilities.

As new science emerges and more data become available, the Department will continue to exercise its statutory authorities to regulate PFAS contamination across Department programs. Investigating the financial and economic impacts of regulating these substances, along with environmental and public health impacts, will remain central to the Department's regulatory process. In collaboration with the Commonwealth's multi-agency PFAS Action Team, the Department will continue to encourage sibling agencies to exercise their authorities to protect Pennsylvanians from the adverse health effects associated with exposure to these substances. The minimization or elimination of these substances from use in products in the consumer market will curtail downstream pollution, thereby relieving financial burdens associated with monitoring and treating PFAS borne by entities such as PWSs.

29. Comment: One member of the General Assembly provided comments relative to PFAS use in the oil and gas industry, objecting to exemptions for the oil and gas industry that allow PFAS to be used in drilling fluids. The legislator objects to the exemptions for the oil and gas industry that allow radium and PFAS to be unmeasured, unmonitored, and not tracked, and references a recent study by the Physicians for Social Responsibility that found that PFAS has been used in more than 1,200 wells in six states and comments that there is a lack of disclosure concerning chemicals used in fracking. (6)

Response: To the extent this comment is addressing exemptions in Federal law, this comment is outside the scope of this rulemaking. To the extent that the legislator seeks to address how well operators report chemical additives used in hydraulically fracturing oil and gas wells, this comment is also outside the scope of the rulemaking; however, in Pennsylvania, the 2012 Oil and Gas Act contains the applicable chemical disclosure requirements. See 58 Pa.C.S. §§ 3222—3222.1.

30. **Comment:** One member of the General Assembly expressed concern about the use of PFAS in drilling oil and gas wells. (5)

    Response: The Department has considered this comment; however, this comment is outside the scope of this rulemaking. See the Department's response to Comment #29 for related discussion.

31. **Comment:** One member of the General Assembly provided comments expressing concern about contamination from PFAS used in fracking fluids. The legislator is concerned that there is no way to know the extent of contamination related to PFAS used in fracking fluids because they are considered proprietary and the Solid Waste Management Act contains a "leachate loophole" excluding oil and gas companies from testing waste prior to disposal in landfills. The legislator objects to the practice of spreading oil and gas wastewater on dirt and gravel roads because there is no way to determine whether that wastewater contains PFAS. (7)

    Response: To the extent that the legislator is concerned about confidential proprietary information, this comment is outside the scope of the rulemaking; however, in Pennsylvania, the 2012 Oil and Gas Act contains the applicable chemical disclosure requirements. See 58 Pa.C.S. §§ 3222—3222.1. To the extent the comment addresses needed testing for waste prior to disposal, this comment is outside the scope of this rulemaking. To the extent that the legislator is concerned about road spreading activities, this comment is outside the scope of this rulemaking.

32. **Comment:** Legislators, EPA Region 3, and numerous other commentators expressed support for the proposed rulemaking. Some commentators simply stated that they were writing in support or in favor of the rule, or that they applaud the Department's efforts. Some comments in support of the proposed rulemaking included general statements about the harmful effects and persistence of PFAS and the urgency of adopting MCLs. Some comments included statements urging the EQB to act quickly to adopt the proposed MCLs. Many commentators who commented in support of the proposed rulemaking also included additional comments recommending changes to the proposed rule; those additional comments are addressed separately in this document. (3, 8, 12-16, 19, 20, 23, 25, 27, 29, 32, 35, 36, 41-43, 52-56, 58-61, 67, 70, 75, 76, 87, 95-104, 106-108, 11, 111, 113-116, 118, 120-122, 131, 133, 135, 137-139, 142, 155, 156, 159, 161, 163, 166, 167, 169, 171, 172, 174-1049, 1054-1806, 2777-3131)

    Response: The Department acknowledges these comments and appreciates the commentators' support.

33. Comment: EPA Region 3 noted that "The Consumer Confidence Report (CCR) provisions for community water systems and bulk water systems are consistent with Federal/current CCR data table requirements concerning how to present data, health effects and sources of the contaminant. The CCR health effects language is also consistent with the public notice health effects language requirements." (12)

Response: The Department appreciates EPA's confirmation that the CCR provisions and health effects language in the rulemaking are consistent with Federal CCR requirements.

34. Comment: EPA Region 3 noted that "The Public Notification (PN) Rule provisions for community water systems and bulk water systems are consistent with Federal/current PN requirements regarding content, delivery, and timing of notice (§ 109.409 Tier 2 Public Notice). The PN health effects language is also consistent with the public notice health effects language requirements." (12)

Response: The Department appreciates EPA's confirmation that the PN provisions and health effects language in the rulemaking are consistent with Federal PN requirements.

General Comments

35. Comment: A few commentators expressed concern that the PFAS Sampling Plan, which the Department used to gather occurrence data and inform the rulemaking process, was insufficient, and that the use of targeted sampling is unscientific and biased. Commentators stated that only a small percentage of public water systems were included in the sampling plan and that many additional water supplies need to be tested. (24, 32, 33, 35, 36, 52, 62, 64, 73, 152)

Response: The Department disagrees with the implication that the sampling plan was unscientific and biased but acknowledges these comments. The purpose of the PFAS Sampling Plan was to provide data regarding the occurrence and distribution of PFAS in public water systems (PWSs) in Pennsylvania. The Sampling Plan was not intended to produce a full assessment of all PWSs in Pennsylvania in which PFAS might be detected if sampled. Sampling all PWSs in the Commonwealth for PFAS was not the purpose of this sampling program nor was funding available to do a comprehensive assessment of PFAS in all 8,373 PWSs in Pennsylvania. However, the Department does not agree that the limited, targeted sampling renders the results insufficient.

To select and prioritize sites for sampling, the Department first narrowed the potential sampling pool to the 3,040 community and nontransient noncommunity water systems, due to the increased relative risk of exposure to consumers who regularly consume water from these systems. The Department then conducted a literature review to assess the relative risk from potential sources of PFAS contamination (PSOCs) from various industries and land uses, as described in the PFAS Sampling Plan. The Department used the literature review to conduct targeted sampling near those expected PSOCs, rather than sampling from PWS sources near known PSOCs.

Using a GIS project designed for this sampling plan, PWS sources within 0.5 miles from suspected PSOCs were identified; this was later expanded to 0.75 miles. The initial sampling pool included 493 PWS sources considered to be targeted sites due to their proximity to a PSOC. The sampling plan also identified baseline sources to serve as a control group. Baseline sources were located within a forested watershed and at least five miles from any know PSOCs. Baseline sites ultimately accounted for approximately 10% of the sites in the sampling pool. To minimize duplication of previous sampling efforts, any PWS sources within 0.5 miles of known PFAS contamination sites were excluded from the sampling pool if the sources were previously monitored and assessed for PFAS (PA DEP, 2019).

Along with data collected as part of this PFAS Sampling Plan, the Department also considered 23 results with PFAS detections from monitoring conducted by PWSs in Pennsylvania under the EPA's Third Unregulated Contaminant Monitoring Rule (UCMR3). Because the reporting limits used for UCMR3 were much higher than current reporting limits, the Department did not consider UCMR3 data that was not detected.

Ultimately, the Department considered results from a total of 435 sites (372 targeted sampling sites, 40 baseline sites, and 23 UCMR3 sites) representing 352 PWSs in the evaluation of occurrence data. The Department acknowledges that because the sampling plan included predominantly targeted sites near PSOCs, the occurrence data may overestimate the actual number of PWSs in Pennsylvania with PFAS detections.

Upon approval of the Safe Drinking Water PFAS MCL rule, all community and nontransient noncommunity PWSs, as well as bottled, vended, retail, and bulk water systems, will be required to conduct monitoring for the PFAS for which an MCL is established, according to the monitoring requirements in the rule. In addition, all community and nontransient noncommunity water systems serving a population of greater than or equal to 3,300, and a representative set of systems serving a population of less than 3,300 will be required to conduct monitoring for PFAS under the EPA's Fifth Unregulated Contaminant Monitoring Rule (UCMR5) between 2023 and 2025. This monitoring will include 29 PFAS analyzed via EPA Methods 533 and 537.1 and will generate additional occurrence data for future consideration (US EPA, 2021c).

36. Comment: One commentator expressed concern that not only was the sampling plan biased and not representative of statewide occurrence of PFAS, but that, even so, the Department's PFAS occurrence data "show infrequent and low detections of the sampled PFOA and PFOS," and therefore the occurrence data do not support the Department's proposed MCLs. (64)

Response: As described in the PFAS Sampling Plan, the public water system (PWS) entry points (EPs) selected for sampling were based on a literature review of potential PFAS sources in this Commonwealth. Creating an inventory of all PFAS contamination statewide was not the purpose of this sampling program nor was funding available to do a comprehensive assessment of PFAS in all 8,373 PWSs in Pennsylvania.

The sampling plan specifically stated that "The purpose of this plan and the sampling to be performed as a result of this plan is to provide additional data regarding the occurrence of PFAS in PWSs in Pennsylvania" (PA DEP, 2019). To minimize duplication of previous sampling

efforts, any PWS sources within 0.5 miles of known PFAS contamination sites were excluded from the sampling pool if the PFAS sources were previously monitored and assessed for PFAS. The sampling plan was based on a literature review of potential sources of contamination (PSOCs) rather than known sources. The Department used the literature review to conduct targeted sampling near those PSOCs. The sampling plan also included a control group (referred to as baseline sources). Results from the baseline samples demonstrated that PFAS were detected in only two out of 40 baseline samples.

Therefore, the PFAS analytical results from the PFAS Sampling Plan cannot be construed as comprehensive statewide PFAS data, but rather provide occurrence data used to inform the rulemaking process (see the Department's response to Comment #35 for related discussion on the PFAS Sampling Plan).

The occurrence data show that 5.1% of sites sampled exceeded the MCL for PFOS of 18 ppt, and 5.7% of sites sampled exceeded the MCL for PFOA of 14 ppt. Accounting for co-occurrence, a total of 7.4 % of the sites exceeded one or both MCLs (PA DEP, 2021c). Recent research suggests that the 2016 EPA Combined Lifetime Health Advisory Level (HAL) for PFOA and PFOS is not sufficiently protective against adverse health effects. Therefore, the Department believes it is imperative to move forward with the MCLs in order to improve public health protection for a significant number of Pennsylvanians.

37. Comment: A few commentators expressed concern that the Department developed MCLs that they believe are not based on scientific studies or cannot be supported by adequate research and supporting data. One commentator stated: "PA DEP has created an arbitrary number with these levels with no scientific research at all to justify the numbers" and "We would not be as concerned with the proposed numbers if PA DEP could actually scientifically back up the reason for the proposed numbers." Another commentator stated a new rule should be "implemented only after full consideration of scientifically based water quality and health review and studies, including the recommendations of water industry professionals, and rejecting any non-health and science-based influences" and expressed concern "when water quality standards are developed and imposed without adequate research and supporting data." (18, 19, 24, 62, 73)

Response: The Department disagrees that the rulemaking is not supported by science and data. As explained in the preamble, the Department must follow a rigorous process when setting an MCL. An MCL rulemaking must be based on available data, studies, and science, and must consider all factors as required by the Federal Safe Drinking Water Act (Federal Act) (42 U.S.C.A. §§ 300f—300j-27) and the Commonwealth's Regulatory Review Act (RRA) (71 P.S. §§ 745.1—745.14). Among other things, the Department must consider health effects, occurrence data, technical limitations such as available analytical methods and detection and reporting limits, treatability of the contaminant and available treatment technologies, and costs and benefits (71 P.S. § 745.5b) (EQB, 2022).

In developing the proposed rulemaking, the Department took numerous steps to make sure that it was following the required process, and appropriately using science and data to make decisions. In 2019, the Department's Safe Drinking Water Program moved forward with two key

projects to advance its knowledge of PFAS—the PFAS Sampling Plan and PFAS Toxicology Services Contract. To scientifically consider health effects, the Department's Safe Drinking Water Program executed the PFAS Toxicology Services Contract with Drexel University in December 2019 to: review other state and Federal agency work on maximum contaminant levels (MCLs); independently review the data, science, and studies; and develop recommended maximum contaminant level goals (MCLGs) for select PFAS, which are the basis for setting MCLs. See the Department's response to Comment #9 for more information on the expertise of the members of the Drexel PFAS Advisory Group (DPAG) and their selection of critical endpoints and studies. To scientifically gather occurrence data for consideration, the Department's Safe Drinking Water Program developed and implemented the PFAS Sampling Plan, which was intended to prioritize PWS sites for PFAS sampling and generate Statewide occurrence data. That occurrence data was used to inform the decision on which PFAS to regulate and estimate the number of PWSs that may potentially have levels of PFAS in excess of MCL levels.

To assess the technical limitations such as available analytical methods and detection and reporting limits along with treatability and treatment technology considerations, the Department conducted several surveys to gather information. Surveys were conducted of laboratories accredited by Pennsylvania for one or more analytical methods for PFAS, systems in Pennsylvania with existing PFAS removal treatment installed, PFAS removal treatment manufacturers, and members of the ASDWA. Assessment of technical limitations was also informed by the Department's review of a PFAS case study published by the American Water Works Association (AWWA). The Department used the information gathered from the lab survey to consider available analytical methods, minimum reporting levels, laboratory capacity and analytical costs. The information gathered from the other surveys and review of the AWWA-published case study was used to evaluate treatment technologies, costs of installation, and maintenance of treatment options. This information was also used along with the occurrence data to conduct the cost and benefit analysis.

Monitoring requirements for PFAS in the rulemaking were based on the monitoring requirements for organic contaminants that already have MCLs. As described in the Department's response to Comment #14, this monitoring framework is based on the established strategy for setting monitoring frequencies for contaminants that cause chronic health risks from long-term exposure.

The Department acknowledges that the science on PFAS is evolving. However, in the interest of public health protection, it is the Department's viewpoint that it is imperative to move forward with this rulemaking at this time, which was based on the most recent scientific studies and data available at the time it was developed, and which took health effects, occurrence data, technical limitations, treatability, and costs and benefits into consideration. The Department recognizes that newer studies on the toxicity and health effects of several PFAS are on the horizon. The Department will continue to evaluate the emerging science and recommendations from experts in the field of toxicology. Also, as more water systems begin to conduct monitoring for PFAS, there will be more occurrence data to evaluate. The EPA's Fifth Unregulated Contaminant Monitoring Rule (UCMR5) includes nationwide monitoring for 29 PFAS by water systems serving more than 3,300 persons between 2023 and 2025 (US EPA, 2021c). According to the

EPA PFAS Strategic Roadmap, the agency is planning on establishing a national primary drinking water regulation for PFOA and PFOS, with a proposed rule in the fall of 2022 and a final rule in the fall of 2023 (US EPA, 2021b). EPA is also in ongoing consultation with the EPA's Science Advisory Board in the evaluation of additional PFAS and groups of PFAS. The Department recognizes that there will be a need to continue to reevaluate the science and data relative to PFAS. At a minimum, as a primacy agency, the Department will need to evaluate a Federal rule once it is published to make sure our state rule is at least as stringent as the Federal rule, or make the necessary updates to our state rule.

38. Comment: A few commentators expressed concern with the compliance monitoring cost estimates included in the proposed rulemaking, and that actual costs will ultimately be higher than those estimates. One commentator stated that the Department "assumes that no public water system will be required to conduct quarterly sampling after the initial monitoring has been conducted during the first year" in calculating cost estimates. (15, 60, 65)

Response: To calculate compliance monitoring cost estimates, the Department conducted a survey of laboratories accredited by Pennsylvania to analyze samples via one of the three approved methods included in the rulemaking. As explained in the preamble to the proposed rulemaking, based on the results of that survey, the Department used an average cost of $616 per sample to calculate overall compliance monitoring costs. In response to the survey, the actual costs per sample varied greatly, ranging from $325 to $750 per sample (EQB, 2022; PA DEP, 2021b). Because the analytical methods all require collection and analysis of a field reagent blank (FRB), those costs included analysis of the associated FRB. An additional fee for sample collection was also figured into the overall average cost per sample, as described in the preamble. Therefore, the average cost of $616 per sample used in compliance monitoring cost estimate calculations is just that: an average. Some PWSs may pay more per sample and some may pay less. It will be up to each PWS to utilize the services of an accredited laboratory that meets their specific needs in terms of services provided, costs, etc.

As noted in the preamble to the proposed rulemaking, there are a few potential cost reduction opportunities which became apparent from the survey. Sample collection by the laboratory is an additional fee that was factored into the estimated cost per sample. A PWS that collects their own sample and delivers it to the laboratory will save the sample collection fee. Approximately half of the responding laboratories offer a cost reduction for reporting fewer analytes than included in the method, which would provide costs savings since monitoring and reporting is only required for two analytes (PFOA and PFOS) under the rulemaking. There is also potential cost saving for PWSs with no detections in the sample, since the analytical methods do not require the FRB to be analyzed in the event that there are no detections in the associated sample.

The Department disagrees with the comment that the compliance monitoring cost estimates did not include quarterly monitoring beyond the initial monitoring year. The Department used the occurrence data to estimate the percentage of public water systems (PWSs) that would have PFOA or PFOS detections and therefore be required to continue to conduct quarterly monitoring. Those percentages were applied to the number of entry points (EPs) required to conduct compliance monitoring under the rule, in order to include continued quarterly monitoring in the cost estimates. As noted in the preamble, based on the occurrence data, it is

assumed that up to 34.9% of all EPs will have a detection of PFOA or PFOS, or both, at or above the relevant MRL; this equates to 658 EPs of the systems conducting initial monitoring in 2024 (year 1) that will need to continue quarterly repeat monitoring in year 2, and 663 EPs of the systems conducting initial monitoring in 2025 (year 2) that will need to continue quarterly repeat monitoring in year 3 (EQB, 2022). The remaining systems (1,227 EPs in year 1 and 1,237 EPs in year 2) were assumed to conduct annual repeat monitoring in each year following initial monitoring, but this overestimates the repeat monitoring requirements and costs after the initial monitoring because, for EPs where initial monitoring results do not detect PFOA or PFOS, the frequency of repeat monitoring is reduced to once every three years.

The Department also considered PWSs that may exceed one or both MCLs in the compliance monitoring cost estimates. Systems with EPs that exceed one or both MCLs may require treatment, which would require the system to conduct ongoing repeat compliance monitoring at least annually. Using the noncompliance rate of 7.4% from the occurrence data (as described in section D of the preamble), a total of 280 EPs are estimated to require ongoing repeat compliance monitoring: 139 EPs from initial year 1 and 141 EPs from initial year 2 (EQB, 2022). However, this is likely an overestimate because: (1) systems may have options other than installing treatment to address concentrations of PFOA or PFOS, or both, above the relevant MCL; and (2) the occurrence data sampling predominately targeted sites near potential sources of PFAS contamination, so the exceedance rate in the occurrence data may overestimate the exceedance rate for other PWSs in this Commonwealth that were not included in the occurrence data. For total compliance monitoring cost estimates, the ongoing annual compliance monitoring for EPs where treatment is installed was assumed to begin in the third year of monitoring (year 3 or year 4 overall).

Table 15 in the preamble to the proposed rulemaking, copied below, summarizes the compliance monitoring cost estimates using the above assumptions and an estimated average cost of $616 per sample. As noted in the preamble, this table does not include cost estimates for performance monitoring which may be required per special permit condition for PWSs that install PFAS removal treatment. Performance monitoring costs are considered part of treatment operation and maintenance costs because performance monitoring is used to make operations decisions, such as when to change out treatment media.

	Total # EPs	Quarterly Initial EPs	Annual Repeat EPs	Quarterly repeat EPs	Quarterly compliance monitoring cost	Annual compliance monitoring cost	Total yearly compliance monitoring cost
Year 1	1885	1885	0	0	$4,644,640	$0	$4,644,640
Year 2	1900	1900	1227	658	$6,302,579	$755,915	$7,058,495
Year 3		0	3122	663	$1,633,878	$1,923,090	$3,556,969
Year 4		0	3785	0	$0	$2,331,560	$2,331,560

39. Comment: A few commentators requested that the Department consider limiting the requirement for a field reagent blank (FRB) with every sample collected for PFOA and PFOS analysis via one of the approved methods. Commentators noted the additional cost associated

with FRB analysis and that cost estimates must take that additional cost into account. Commentators also questioned the value of the FRB for a water system with known or expected PFAS detections or previously installed treatment. (13, 23, 29)

Response: Consistent with Federal standards, the Department included approved analytical methods for PFOA and PFOS in the proposed rulemaking at § 109.304(f). Normally the Department would incorporate approved methods specified by the EPA, however unless and until the EPA codifies approved methods for PFAS, it was necessary for the Department to do so (see the Department's response to Comment #22). The approved methods included in the rulemaking are EPA Methods 533, 537.1, and 537 version 1.1. All samples collected for compliance with the rulemaking must be analyzed by a laboratory accredited in Pennsylvania for at least one of these methods.

Each of the approved methods requires the collection of a field reagent blank (FRB) with every sample. An FRB is defined in Method 537.1, Section 3. Definitions, as "An aliquot of reagent water that is placed in a sample container in the laboratory and treated as a sample in all respects, including shipment to the sampling site, exposure to sampling site conditions, storage, preservation, and all analytical procedures. The purpose of the FRB is to determine if method analytes or other interferences are present in the field environment" (Shoemaker, 2018). The other approved methods include equivalent FRB definitions (Rosenblum, 2019; Shoemaker, 2009). If analysis of the FRB shows detections of an analyte, it is an indication that cross contamination likely occurred at some point during sample collection, handling, transport, or analysis of the FRB, and may also be indicative of cross contamination of the corresponding sample.

While all three approved analytical methods include the requirement for collection of an FRB, they also all include a provision that analysis of the FRB is only required if the corresponding sample result is above the minimum reporting level (MRL) for any analytes. As stated in Method 537.1, "Analysis of the FRB is required only if a Field Sample contains a method analyte or analytes at or above the MRL" (Shoemaker, 2018). In other words, if the method analytes are not detected in the sample, there is no need to analyze the FRB. Since the purpose of the FRB is to ensure that sample results are not affected by inadvertent cross contamination, that purpose becomes unnecessary for a sample with no detections. The rulemaking includes MRLs of 5 ppt for PFOA and PFOS.

Laboratories accredited to conduct analyses using specific methods must demonstrate that they follow method requirements to maintain accreditation. Therefore, in accordance with method requirements, an FRB must be collected and submitted to an accredited laboratory with every sample collected for compliance with the proposed MCLs for PFOA and PFOS. However, in accordance with the approved methods, for samples with no detection of PFOA or PFOS above the proposed MRL of 5 ppt, the corresponding FRB would not need to be analyzed.

With regard to cost estimates for the rulemaking, the Department did include the additional cost of FRB analysis when calculating estimates for compliance monitoring costs. See the Department's response to Comment # 38 for more information about monitoring cost estimates for the rulemaking.

40. **Comment:** A few commentators expressed concern with laboratory and sampling errors and cross contamination during sampling and analysis for PFAS, particularly in the parts per trillion range. One commentator recommended that the Department develop "a regulatory scheme that accounts for the variability in and limits of current laboratory testing." Another commentator specifically expressed concern with potential laboratory and sampling inaccuracies relative to EPA Method 533 for PFOS and PFOA at levels in the parts per trillion range and referenced Table 12 in the method as evidence. The commentator stated that these potential inaccuracies "may cause undue concern and treatment costs by consumers of well water and municipal potable water suppliers." (66, 173)

    Response: The Department acknowledges these comments but disagrees with the implication that laboratory and sampling error are significant enough to impact laboratories' ability to accurately measure and report PFAS at and above the MRL in the rulemaking. Any laboratory method has some level of variability. There are numerous sources of error that can introduce variability in laboratory data, including the sampling environment, sample matrix and water chemistry, the analyst, the instrumentation, and the laboratory environment. When a laboratory seeks to become accredited to conduct drinking water analysis and report data for compliance purposes, the laboratory must demonstrate proficiency with the specific methods for which they are seeking accreditation through the laboratory accreditation process, including a demonstration of precision and accuracy. Once accredited, in order to maintain accreditation, the laboratory must continue to demonstrate proficiency with the analytical methods. Public water systems (PWSs) are only permitted to utilize the services of an accredited laboratory for analysis of samples used for compliance purposes. In this way, the Department can be confident that analytical data submitted on behalf of a PWS by an accredited laboratory are accurate, precise, and legally defensible.

    The inherent variability and error present in any analytical method is often exacerbated at very low levels of analyte concentration. The rulemaking includes a regulatory minimum reporting level (MRL) of 5 parts per trillion (ppt) for both PFOA and PFOS for each of the approved methods. In order to maintain accreditation, a laboratory must demonstrate that it can achieve accurate results at or below that level. Some laboratories may be able to accurately quantify at levels lower than the regulatory MRL. The reason for setting the MRL is to minimize the impact of inherent laboratory error on data submitted for compliance, particularly at very low levels.

    The Department disagrees with the assessment that Table 12 in EPA Method 533 demonstrates that the method is subject to a level of inaccuracy that may result in increased treatment costs. Table 12 displays single laboratory precision and accuracy data for a drinking water matrix from a surface water source (Rosenblum, 2019). Precision and accuracy data for reagent water and finished ground water are presented separately in Tables 8 and 10 in the method, respectively. These tables present the mean percent recovery and percent relative standard deviation of samples fortified with PFAS at concentrations of 10 and 80 ng/L or ppt. The tables demonstrate that the laboratory was able to achieve data that were accurate and precise in a variety of sample matrices.

The Department also disagrees with the implication that potential inaccuracies may result in increased treatment costs. Since the MRL is 5 ppt and the MCLs are 14 ppt and 18 ppt for PFOA and PFOS respectively, any small amount of inherent error at a very low concentration could potentially result in a low-level detection but would not result in an MCL exceedance. Treatment would not generally be required for a PWS with detections of PFOA or PFOS below the MCL. (See the Department's response to Comment #16 for more on possible corrective actions as a result of an MCL exceedance.)

In response to the comment concerned with sampling inaccuracy in addition to laboratory inaccuracy, because PFAS are found in so many consumer products, sample collectors do need to be aware of the potential for cross contamination and take steps to mitigate that potential during sample collection. The Department intends to conduct training to educate sample collectors on ways to minimize the potential for cross contamination during sample collection. This training would need to occur in 2023, prior to initial compliance monitoring for systems serving more than 350 persons, which would begin on January 1, 2024.

41. **Comment:** A few commentators expressed concern with requiring water systems to report both the proposed MCL and MCLG for PFOA and PFOS in their annual Consumer Confidence Report (CCR) in addition to levels detected. Commentators are concerned that "confusion between the two sets of standards for consumers of public water systems is a possibility" and that it is inappropriate to require systems to report that they exceed the MCLG if they are in compliance with all regulatory requirements. (28, 65)

    Response: The Consumer Confidence Report (CCR) is an annual report intended to inform and educate consumers on the quality of their drinking water. CCR requirements are found in 40 CFR Part 141 and incorporated into § 109.416. However, at this time, there is no federal standard for PFAS and therefore no existing reporting requirements for PFAS in CCRs at the federal level. Therefore, in order to be consistent with federal standards, the Department must include CCR reporting requirements for PFAS in this rulemaking, and the language in the CCR with respect to PFAS must be equivalent to the language and requirements utilized for other contaminants.

    The standard reporting requirement is for the CCR to include both the MCLG and the MCL for each contaminant, which is intended to inform the consumer. Definitions are included in the CCR to explain the difference between MCL and MCLG to consumers (PA DEP, 2018a and 2018b). Because the CCR provides information on where drinking water comes from, what has been detected in the water, and how consumers can help protect their source of water, the CCR needs to include all detected results. Some of these results may be over the MCLG but not the MCL.

42. **Comment:** One commentator noted the health effects language for public notice, found in proposed § 109.411(e)(1)(ii) and (iii), and recommended that the health effects language be removed from the rulemaking and instead incorporated into a guidance document, given the evolving understanding of the health effects of PFAS. (18)

Response: The existing health effects statements for public notices, which are required after certain violations, are established through § 109.411(e)(1), which states "Public water systems shall include in each public notice appropriate health effects language. This subchapter incorporates by reference the health effects language specified in 40 CFR Part 141, Subpart Q, Appendix B (relating to standard health effects language for public notification), corresponding to each primary MCL, MRDL and treatment technique violation listed in 40 CFR Part 141, Subpart Q, Appendix A (relating to NPDWR [National Primary Drinking Water Regulations] violations and other situations requiring public notice), and for each violation of a condition of a variance or exemption, unless other health effects language is established by regulations or order of the Department."

Specific health effects language for each regulated contaminant is written into 40 CFR Part 141, Subpart Q, Appendix B, even though additional scientific research could result in changes to the established health effects. The table in 40 CFR Part 141, Subpart Q, Appendix B does not yet have entries for PFOA or PFOS, so in accordance with § 109.411(e)(1), the health effects language is instead established by the regulations of the Department, in § 109.411(e)(1)(ii) and § 109.411(e)(1)(iii). By specifying the health effects language in the rule itself, the Department is following the EPA's convention.

43. Comment: One commentator noted the health effects language for CCRs, found in proposed § 109.416(3.1)(ii), and recommended that the health effects language be removed from the rulemaking and instead incorporated into supplemental technical guidance, since the understanding of health effects for these compounds is constantly evolving. (18)

Response: The existing health effects statements for public notices, which are required after certain violations, are established through § 109.416(3), which states "Except as noted in subparagraphs (i)–(v), the annual report that a community water system provides to its customers shall contain all of the information, mandatory language and optional text specified by the EPA under 40 CFR 141.153 and 141.154 (relating to content of the reports; and required additional health information), which are incorporated by reference, and under 40 CFR 141, Subpart O, Appendix A (relating to regulated contaminants), which is incorporated by reference, unless other information, mandatory language or optional text is established by regulations or order of the Department."

According to 40 CFR 141.153(d)(6), when there is an MCL violation for a contaminant, a CCR must include the specific health effects language for that contaminant provided in 40 CFR 141, Subpart O, Appendix A. The table in 40 CFR Part 141, Subpart O, Appendix A does not yet have entries for PFOA or PFOS, so in accordance with § 109.416(3), the mandatory health effects language is instead established by the regulations of the Department in § 109.416(3)(3.1)(ii) by reference to § 109.411(e)(1)(ii) and § 109.411(e)(1)(iii). By specifying the health effects language in the rule itself, the Department is following the EPA's convention.

44. Comment: One commentator noted the requirement for representative sampling in proposed § 109.303(a)(6)(i) and recommends that the Department clarify requirements for water systems that routinely change their source combinations. (28)

Response: In the final-form rulemaking, proposed § 109.303(a)(6)(i) has been integrated into § 109.303(a)(6) after proposed § 109.303(a)(6)(ii) was removed in response to comments received regarding the need for properly trained sample collectors (see the Department's response to Comment #21).

The cited text in § 109.303(a)(6) matches exactly with existing text in § 109.303(a)(4) for contaminants that already have federal MCLs, so this requirement follows established requirements for other contaminants. Representative monitoring for PFOA and PFOS will not be different from representative monitoring for contaminants that currently have MCLs.

Monitoring for compliance with the PFOA and PFOS MCLs should also be done according to a public water system's comprehensive monitoring plan to ensure all sources are included in monitoring. Comprehensive monitoring plans were due to the Department by August 19, 2019. For more information on comprehensive monitoring plans, see § 109.303(i) and § 109.718 and guidance available at https://www.dep.pa.gov/Business/Water/BureauSafeDrinkingWater/DrinkingWaterMgmt/Regulations/Pages/Proposed%20General%20Update%20and%20Fees.aspx.

45. **Comment:** One commentator recommended that quarterly repeat monitoring for each PFAS only be required for each EP with a detection at or above 50% of the MCL. The commentator noted the current cost of sampling and analysis for PFAS as the reason for this recommendation. (21)

Response: In accordance with § 109.301(16)(ii), the Department considers a PFAS to be detected when it is "at a level equal to or greater than its corresponding MRL [minimum reporting level] as defined in § 109.304(f)." The MRLs defined in § 109.304(f) are 5 ng/L for both PFOA and PFOS. Individual laboratories may be able achieve lower MRLs, but whether or not results are considered detections will be based on the regulatory MRLs of 5 ng/L. Results should be rounded to the nearest ng/L before comparing them with the MRL.

Following a detection, quarterly monitoring for at least four consecutive quarters is the existing requirement for the other groups of regulated organic chemicals, the volatile synthetic organic chemicals (VOCs) and synthetic organic chemicals (SOCs) as written in § 109.301(5)(iii) and § 109.301(6)(ii), respectively. For VOCs, a detection occurs when a VOC is at a concentration equal to or greater than 0.0005 mg/L, as specified in 40 CFR 141.24(f). For SOCs, a detection occurs when an SOC is at a concentration greater than its detection limit specified by the EPA in 40 CFR 141.24(h)(18). Quarterly monitoring is done for at least four consecutive quarters and until a detected contaminant is shown to be reliably and consistently below the MCL, or until an MCL violation occurs, which would require additional follow up monitoring and corrective actions. For VOCs and SOCs, reliably and consistently below the MCL, as defined in § 109.1, means that each sample result is less than 80% of the MCL. For PFAS, if the necessity for repeat quarterly monitoring was based on 50% of the MCL instead of a reporting level or detection limit, then this would be a significant deviation from what is already being done for the other regulated organic chemicals.

The phrase “reliably and consistently below the MCL” hints at the purpose of quarterly monitoring following a detection. The purpose is to see if a detected contaminant will never be detected again, detected at a consistent concentration well below the MCL, or detected at a concentration close to or above the MCL. Although known sources of PFOA or PFOS can be established, their concentration in source water can fluctuate over time, and thus annual or less frequent monitoring is not sufficient to establish the range of concentrations within a reasonable timeframe.

46. Comment: One commentator noted that while the proposed rulemaking identifies the effective date of the rule, it does not list a compliance date. The commentator recommended including a statement in the proposed rulemaking to clarify that compliance will begin “after initial monitoring.” (28)

Response: In the interest of timely realizing the public health benefits of this rulemaking, public water systems (PWSs) shall comply with the MCLs for PFOA and PFOS beginning on the effective date that will be provided in § 109.202(a)(4)(i) in the final rule, which is expected to be a date in early 2023. Compliance with the MCLs will thus be required before initial monitoring starts in 2024 or 2025.

In accordance with § 109.701(a)(3)(i), if a sample is taken on or after the effective date of the rule, and the result indicates an exceedance of a PFAS MCL, a public water supplier shall report it to the Department within one hour of discovery. One-hour reporting should be done whether or not the laboratory is accredited by the Department for EPA Method 533, EPA Method 537.1, or EPA Method 537 Version 1.1. Thus, after the effective date of this rule, if a PWS discovers that a sample taken for the EPA’s Fifth Unregulated Contaminant Monitoring Rule (UCMR5) has a PFOA or PFOS result that exceeds the respective MCL, then the supplier shall report it to the Department within one hour of discovery.

If, for any reason, a system is taking entry point samples on or after the effective date, but prior to its initial monitoring period, and these samples are being analyzed for PFOA and/or PFOS at a laboratory that *is* accredited by the Department, then compliance will be determined according to § 109.301(16)(ix). If these samples are being analyzed for PFOA and/or PFOS at a laboratory that *is not* accredited by the Department, then, in the event of an MCL exceedance, § 109.4 (General requirements) and/or § 109.302 (Special monitoring requirements) will be used to ensure there is safe drinking water at the entry point.

47. Comment: One commentator expressed concerns with supply chain issues and difficulties obtaining necessary supplies, and the potential impact to a water system that may need to install treatment to achieve compliance with the proposed PFAS MCLs. The commentator noted that delays in receiving equipment and materials may cause delays in meeting compliance schedules. (30)

Response: The Department acknowledges the current supply chain issues and resulting hinderance on acquiring materials necessary for treatment installation. Availability issues for treatment technologies for other contaminants have been dealt with in the past and continue to factor into the permitting process when treatment installation is necessary.

Public water systems are responsible for taking all corrective actions necessary to protect public health. However, when corrective actions are required, timeframes for achieving compliance can be adjusted to accommodate unplanned issues in accordance with the Department's technical guidance document, *Guidelines for Identifying, Tracking and Resolving Violations for the Drinking Water Program* (383-4000-002) (PA DEP, 2006a).

48. Comment: One commentator expressed concern with compliance schedule constraints. The commentator noted that "time to attain compliance should factor in the necessary steps for installation of treatment, including issuance of a request for proposals, contract award and execution, detailed design, permitting, bid advertisement, bid award and contract execution, and construction." The commentator suggests that the Department consider revised compliance schedules in order to allow a reasonable time period to attain full compliance. (30)

Response: Corrective actions for maximum contaminant level (MCL) exceedances are not codified in regulation because they are case specific and may vary based on each individual situation and system-specific considerations, including the level detected, any known or suspected source of contamination, other water sources available, and treatment processes already in place.

Under existing authorities in § 109.701(a)(3)(i), a public water system (PWS) is required to notify the Department within one hour if the system is determined to be in violation of an MCL. An initial consultation with the Department typically occurs upon this notification regarding immediate actions. The Department then issues a notice of violation (NOV) for an MCL violation. The NOV contains requested actions, which may include further consultation on longer term corrective actions.

If a PWS fails to take corrective actions, the Department identifies the ongoing MCL violation as a significant deficiency and notifies the PWS through an NOV, which outlines system responsibilities as stipulated in § 109.717 for responding to significant deficiencies, including required timeframes. However, the Department may approve an alternate schedule by entering into a Consent Order and Agreement with the system. See the Department's response to Comment #16 for more information on corrective actions and compliance schedules.

The Department also acknowledges that supply chain issues have hindered PWSs abilities to acquire materials necessary for treatment installation. See the Department's response to Comment #47 regarding supply chain issues and adjustments to compliance schedules.

49. Comment: One commentator noted that there are other sources of PFAS besides drinking water and expressed concern with the fact that "reducing the levels in water will not eliminate exposure" to PFOA or PFOS. (26)

Response: The Department acknowledges that Pennsylvanians can be exposed to PFAS via many exposure routes in addition to drinking water. Drinking water has been identified as a substantial source of PFAS exposure for many populations, particularly those living near contaminated sites (Sunderland et al., 2019). The Department acknowledges that full implementation of the rule will not eliminate Pennsylvanians' exposure to PFAS. However, the

Department's Bureau of Safe Drinking Water is authorized under Pennsylvania's Safe Drinking Water Act to address PFAS in drinking water. The MCLs for PFOA and PFOS will provide a measurable opportunity to protect public health. In the interest of public health protection, it is the Department's viewpoint that it is imperative to move forward with this rulemaking.

50. Comment: One commentator asked whether the Commonwealth has "conducted a study on human health impacts to residents within Pennsylvania, and if so, what are the results?" (62)

Response: The Department acknowledges this comment but notes that it is outside the scope of this rulemaking. However, the Department notes that in 2020, researches at RTI International, an independent nonprofit research institute, in partnership with the Pennsylvania Department of Health (DOH), Temple University, and Brown University, received a grant from the Agency for Toxic Substances and Disease Registry (ATSDR), a federal public health agency of the U.S. Department of Health, to study PFAS levels in adults and children living in the vicinity of the former Naval Air Station Joint Reserve Base Willow Grove. The target subjects of this study live in 11 municipalities in eastern Montgomery County and western Bucks County.

The RTI/DOH joint study began in 2021, intending to conduct a health study on 1,000 adults (aged 18 and older) and 300 children (aged 4-17) who resided in the geographic study area between 2005 and 2017. The health study of the area surrounding the Willow Grove base, referred to by the ASTDR as the "PA PFAS Multi-site Health Study" (https://papfas.rti.org/), is one of seven study areas in the nation included in the $7 million ATSDR program evaluating PFAS in adults and children residing around known PFAS hotspots.

The health parameters being investigated in the study's subjects are PFAS levels in blood, health measures like thyroid hormone levels, liver function, and medical history (including personal and family history of cancer). As of August 2022, the PA PFAS Multi-site Health Study was ongoing and had enrolled 737 adult participants (73% of goal) and 36 children (12% of goal).

51. Comment: A few commentators noted that PFAS contamination in drinking water is an environmental justice issue. One commentator stated that the Department should "assess whether people of color and low-income communities are disproportionately exposed to PFAS chemicals in drinking water." (32, 34, 59)

Response: The Department currently defines an Environmental Justice (EJ) Area as any census tract where 20% or more individuals live at or below the federal poverty line, and/or 30% or more of the population identifies as a minoritized population, based on data from the U.S. Census Bureau and the federal guidelines for poverty.

While not everyone whose drinking water contains PFAS lives in an EJ Area, if the rulemaking is published as final, all public water systems (PWSs) in Pennsylvania will be required to comply with the maximum contaminant levels (MCLs). The Federal Bipartisan Infrastructure Law of 2021 will make funding available for small- and medium-sized water utilities to upgrade their treatment plants to treat PFAS that has been or will be identified in their raw water. This funding will help make it possible for small- and medium-sized water utilities to upgrade their

plants to treat for PFAS without passing the upgrade costs on to their consumers. This funding will also improve the tap water quality for millions of Americans without regard to their race or socioeconomic status, thus ensuring equal protection of drinking water leaving treatment plants for all consumers within the service areas of qualifying drinking water systems.

The proposed rule was published in the *Pennsylvania Bulletin* on February 26, 2022, for a 60-day public comment period. Every resident of Pennsylvania had the opportunity to comment on the proposed PFAS MCL rule. The MCLs will be protective of all Pennsylvanians. If published as final, any PWS in Pennsylvania that experiences an MCL violation will be required to take corrective actions to ensure compliance with the MCLs.

The Department's Safe Drinking Water Program conducted sampling based on the program's 2019 PFAS Sampling Plan. The goal of that sampling plan was to gather data on occurrences of PFAS across the state to ascertain the range of concentrations and their general distribution (PA DEP, 2019). Water systems that the Department sampled as part of the 2019 PFAS Sampling Plan were selected based on proximity to known or suspected sources of PFAS contamination. EJ Areas were not specifically targeted in this sampling plan; however, samples were collected at some treatment plants that serve portions of EJ Areas. In a spatial analysis of the sites selected for the Department's PFAS Sampling Plan, the Department included a mapped layer of EJ Areas in Pennsylvania against the mapped geographical locations of PSOCs. The Department reviewed the overlay to ensure that EJ Areas were not inadvertently excluded from the Sampling Plan and found that approximately 11.5% of the of the wells and intakes identified in the plan were located in EJ Areas.

52. Comment: One commentator asked the following question: "Has Commissioner Ralph V. Yanora- PUC's representative on the National Association of Regulatory Utility Commissioners (NARUC) Committee on Water been advised of this proposed PADEP regulation that will result in increased treatment costs for already proposed 6% increased water bill filings to the PUC throughout SE PA by AquaPA?" (173)

Response: As noted in the Department's response to Comment #6, any rate adjustments for ratepayers that public water systems (PWSs) make to recover costs associated with this rulemaking will depend on the specific costs for each PWS as well as the type and availability of funding.

Additionally, the Department notes that the Pennsylvania Public Utility Commission (PUC) is a member organization of the Department's drinking water advisory board, the Public Water System Technical Assistance Center (TAC) Board. The proposed rulemaking was presented to the TAC Board at the July 29, 2021 meeting; the materials for this meeting can be found at https://www.dep.pa.gov/PublicParticipation/AdvisoryCommittees/WaterAdvisory/TAC/Pages/2021-Meetings.aspx. The current TAC Board member and alternate member representing PUC were both present at that meeting via webinar. At that meeting, the TAC Board voted unanimously to support the Department moving forward with the proposed rulemaking. Additionally, in a letter dated July 30, 2021, the TAC Board expressed support for the proposed rulemaking that included the following statement: "The Public Water System TAC Board supports the Department moving forward in the rulemaking process to present a proposed PFAS

Rule to the Environmental Quality Board." The July 30, 2021 letter is part of the rulemaking documentation that was presented to the Environmental Quality Board during its November 2021 meeting. The Department also presented the draft final-form rulemaking to the TAC Board at the board's July 14, 2022 meeting, at which the PUC member and alternate member were both present, and at which the board again voted unanimously to support the Department moving forward with the final-form rulemaking; materials from that meeting are available at https://www.dep.pa.gov/PublicParticipation/AdvisoryCommittees/WaterAdvisory/TAC/Pages/2022-Meetings.aspx.

53. Comment: One commentator cited minimal risk levels for PFOA and PFOS from the CDC/ATSDR website (https://wwwn.cdc.gov/TSP/MRLS/mrlslisting.aspx) as evidence that the proposed MCLs are too high. The commentator stated that "the amount of PFOA an individual can eat, drink, or breathe each day without a detectable risk to health is only 3 ng/L per day" and "the amount of PFOS … is only 2 ng/L per day." The commentator also stated that "The levels proposed by the Department are much higher than the levels shown to provide a risk to health." (45)

Response: The Department disagrees with the intended implication that the Centers for Disease Control and Prevention minimal risk levels (CDC MRLs) are evidence that the MCLs are too high; the commentator has cited and interpreted the CDC MRLs incorrectly.

The commentator references the Agency for Toxic Substances and Disease Registry (ATSDR) MRLs on the CDC website: https://wwwn.cdc.gov/TSP/MRLS/mrlslisting.aspx. When accessed by the Department on June 27, 2022, the CDC MRLs List was dated February 2022. As listed in ATSDR's list, the CDC MRL for PFOA is:

Route	Duration	MRL	Factors	Endpoint	Draft/Final	Cover Date	CAS Number
Oral	Int.	3 ng/kg/day	300	Develop.	Final	03/2020	335-67-1

The CDC MRL for PFOS is:

Route	Duration	MRL	Factors	Endpoint	Draft/Final	Cover Date	CAS Number
Oral	Int.	2 ng/kg/day	300	Develop.	Final	03/2020	1763-23-1

The table columns can be defined as follows (ATSDR, 2021):

- Route: pathway of exposure to the substance, which here is oral (through the mouth)
- Duration: length of exposure time, which here is intermediate (15–364 days)
- MRL: estimate of the daily human exposure to a hazardous substance that is likely to be without appreciable risk of adverse, noncancer health effects over a specified duration of exposure. CDC MRLs are derived when reliable and sufficient data exist to identify the target organ(s) of effect or the most sensitive health effect(s) for a specific duration for a given route of exposure. The CDC MRL is defined as a point of departure (POD expressed as human equivalent dose (HED)) divided by uncertainty factors (UFs). Potential PODs are no-observed-adverse-effect levels (NOAELs), lowest-observed-adverse-effect level (LOAELs), or the lower limit of the benchmark dose (BMDL).

- Factors: The total UFs used in determining the CDC MRL. ATSDR utilizes uncertainty factors to account for uncertainties associated with: (1) extrapolating from a LOAEL to a NOAEL; (2) extrapolating from animals to humans; and (3) to account for human variability. Default values of 10 are used for each of these categories of uncertainty factors; a value of 1 can be used if complete certainty exists for a particular uncertainty factor category. A partial uncertainty factor of 3 can be used when chemical-specific data decreases the uncertainty. On a case-by-case basis, ATSDR also utilizes modifying factors to account for CDC MRL-specific database deficiencies. Here the total uncertainty factors are 300 for both PFOA and PFOS.
- Endpoint: "Develop." here stands for a developmental endpoint. Developmental outcomes are broken into four categories: pregnancy outcome, birth outcome, neurodevelopment, and sexual maturation. CDC MRLs are generally based on the most sensitive substance-induced endpoint considered to be of relevance to humans.
- Draft/Final and Cover Date: As indicated by the toxicological profile document, the final CDC MRLs for PFOA and PFOS were released in May 2021 and last updated at the cover date of March 2020.
- CAS Number: The CAS Number is the Chemical Abstracts Service unique identification number.

Each HED is computed using HED = POD * DAF, where DAF is the dosimetric adjustment factor. The DAF, in turn, is computed from DAF = K_e * V_d, where K_e is the serum elimination rate constant and V_d is the apparent volume of distribution. K_e can be interpreted as the fraction of a contaminant that is eliminated from a human body per unit time and has units of day^{-1}. V_d can be interpreted as the mass of a contaminant in a human body (e.g., in units of mg) divided by the serum concentration of the contaminant (e.g., in units of mg/L) and then divided by the body mass in kg such that the units of V_d are L/kg. For our discussion here, an important point to recognize is that the kg unit in the denominator of the units for V_d comes from body mass, that is, the total mass of all body components (tissue, fluid, bone, etc.). The kg unit is not for a mass of consumed drinking water.

ATSDR only reports the CDC MRLs and does not make any statements about what an acceptable or goal concentration in drinking water should be. As explained by the ATSDR at https://www.atsdr.cdc.gov/mrls/index.html, "Exposure to a level above the CDC MRL does not mean that adverse health effects will occur" and "It is important to note that CDC MRLs are not intended to define clean up or action levels for ATSDR or other Agencies."

PFOA:

For PFOA, ATSDR (2021) used the LOAEL from a specific study (Koskela et al., 2016) for the POD. The LOAEL/POD is the predicted time weighted average (TWA) serum concentration of PFOA: 8.29 µg/mL = 8.29 mg/L (see p. A-25 and surrounding in ATSDR (2021)). K_e is set to 4.95×10^{-4} day^{-1} and V_d to 0.2 L/kg (see Table A-4 on p. a-13 in ATSDR (2021)). The resulting HED is HED = POD * K_e * V_d = 8.29 mg/L * 4.95×10^{-4} day^{-1} * 0.2 L/kg = 0.000821 mg/kg/day. The CDC MRL is then MRL = HED / UFs. = 0.000821 mg/kg/day / (10*3*10) = 2.74×10^{-6} mg/kg/day or 2.74 ng/kg/day, which rounds to 3 ng/kg/day.

The commentator indicates that the CDC/ATSDR "has estimated that the amount of PFOA an individual can eat, drink, or breathe each day without a detectable risk to health is only 3 ng/L per day," but this is incorrect because the CDC/ATSDR does not actually report such a concentration and it cannot be derived from the actual CDC MRL, which is 3 ng/kg/day. As discussed above, the kg in the denominator of the CDC MRL units is for body mass. It appears that the commentator incorrectly interpreted this kg as a mass of consumed water instead, and then used the fact that 1 L of water has a mass of 1 kg (exactly at 4 °C and slightly less mass at other naturally occurring water temperatures) to incorrectly convert the CDC MRL from 3 ng/kg/day to 3 ng/L/day. This seemingly small error has a significant impact on the interpretation of the CDC MRLs.

In developing the maximum contaminant level goal (MCLG) for PFOA in drinking water, the Drexel PFAS Advisory Group (DPAG) also used Koskela et al. (2016) in their MCLG Report (DPAG 2021), available at https://files.dep.state.pa.us/PublicParticipation/Public%20Participation%20Center/PubPartCenterPortalFiles/Environmental%20Quality%20Board/2021/June%2015/03_PFAS%20Petition/01a_App%201%20Drexel%20PFAS%20Report%20January%202021.pdf. As can be seen in DPAG's Table 3 for "Development of Non-Cancer MCLG for PFOA," DPAG used a somewhat larger value for K_e (8.25175×10^{-4} day^{-1}) than ATSDR and a slightly smaller value for V_d (0.17 L/kg) resulting in a HED of 8.29 mg/L * 8.25175×10^{-4} day^{-1} * 0.17 L/kg = 0.001163 mg/kg/day (DPAG, 2021). ATSDR and DPAG discuss their specific choices for the critical study and values for K_e and V_d. DPAG then computes a reference dose (RfD) which is defined as HED / UFs, so it can be thought of as comparable to the CDC MRL. "The RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily human exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime" (US EPA, May 2016). DPAG computes the RfD using the same uncertainty factors as ATSDR, so RfD = 0.001163 mg/kg/day / (10*3*10) = 3.9×10^{-6} mg/kg/day or 3.9 ng/kg/day.

As explained in DPAG's MCLG Report, to arrive at a PFOA MCLG, which is expressed as a concentration of PFOA in drinking water, there is an additional step of implementing the Goeden model (DPAG, 2021). The MCLG is then used by the Department to determine the PFOA MCL as explained in the preamble to the proposed rule (EQB, 2022). It is incorrect to just take the CDC MRL or an RfD and then immediately make a claim about acceptable maximum drinking water concentrations. Additional steps such as using the Goeden model or scaling for body weight, daily drinking water intake, and relative source contribution (see US EPA, May 2016, Section 3.2.3) must be taken to arrive at a concentration.

PFOS:

For PFOS, ATSDR (2021) used the NOAEL from a specific study (Luebker et al., 2005a) for the POD. The NOAEL/POD is the predicted TWA serum concentration of PFOS: 7.43 µg/mL = 7.43 mg/L (see p. A-45 and surrounding in ATSDR (2021)). K_e is set to 3.47×10^{-4} day^{-1} and V_d to 0.2 L/kg (see Table A-4 on p. a-13 in ATSDR (2021)). The resulting HED is HED = POD * K_e * V_d = 7.43 mg/L * 3.47×10^{-4} day^{-1} * 0.2 L/kg = 0.000515 mg/kg/day. The CDC MRL is

then MRL = HED / UFs. = 0.000515 mg/kg/day / (3*10*10) = 1.72×10^{-6} mg/kg/day or 1.72 ng/kg/day, which rounds to 2 ng/kg/day.

The commentator indicates that the "amount of PFOS that an individual can eat, drink, or breathe each day without a detectable risk is only 2 ng/L per day." Again, this is incorrect because the CDC/ATSDR does not actually report such a concentration, and, as discussed above, 2 ng/L cannot be derived from the actual MRL (2 ng/kg/day) by simply multiplying by the density of water (1 kg/L).

In developing the MCLG for PFOS in drinking water, DPAG used Dong et al. (2011) as their critical study (DPAG, 2021). As can be seen in DPAG's Table 4 for "Development of Non-Cancer MCLG for PFOS," DPAG used a lower serum concentration for the NOAEL/POD (2.36 µg/mL = 2.36 mg/L) than ATSDR, a somewhat larger value for K_e (5.58421×10^{-4} day^{-1}), and a slightly larger value for V_d (0.23 L/kg) resulting in a HED of 2.36 mg/L * 5.58421×10^{-4} day^{-1} * 0.23 L/kg = 0.000307 mg/kg/day (DPAG, 2021). ATSDR and DPAG discuss their specific choices for the critical studies and the values for K_e and V_d. DPAG then computes an RfD using a total uncertainty factor that differs from ATSDR's. One of ATSDR's factors is 10 for concern that immunotoxicity may be a more sensitive endpoint than developmental toxicity while DPAG has a database factor of 3. The resulting RfD is = 0.000307 mg/kg/day / 100 = 3.1×10^{-6} mg/kg/day or 3.1 ng/kg/day.

As explained in DPAG's MCLG Report, to arrive at a PFOS MCLG, which is expressed as a concentration of PFOS in drinking water, there is an additional step of implementing the Goeden model (DPAG, 2021). The MCLG is then used by the Department to determine the PFOS MCL as explained in the preamble to the proposed rule (EQB, 2022). Again, it is incorrect to just take the CDC MRL or an RfD and then immediately make a claim about acceptable maximum drinking water concentrations. Additional steps such as using the Goeden model or scaling for body weight, daily drinking water intake, and relative source contribution must be taken to arrive at a concentration.

54. Comment: One commentator noted that "the reference dosages seem to conflict with the proposed limits making the proposed MCLs look excessively stringent." The commentator calculated "what the reference dosages say is acceptable for the body" using a 70 kg adult consuming 2 L per day and a 19 kg child consuming 1 L per day as evidence. (26)

Response: The Department acknowledges this comment but does not agree with the conclusions drawn. It is incorrect to use a reference dose and directly make a claim about maximum drinking water concentrations. As explained in the Drexel PFAS Advisory Group's (DPAG's) MCLG Report, to arrive at MCLGs for PFOA and PFOS, expressed as a concentration of PFOA or PFOS in drinking water, there is an additional step of implementing the Goeden model or scaling for body weight, daily drinking water intake, and relative source contribution. (DPAG, 2021). The MCLGs are then used by the Department to determine the MCLs as explained in the preamble to the proposed rule (EQB, 2022).

55. Comment: One commentator asked when the Department will "alert citizens they have or may have been drinking contaminated water?" Another stated that, "The public should be made aware of areas where water is not safe to drink." (62, 1090)

Response: Since 2016, the Department has been implementing EPA's HAL of 70 ppt combined for PFOA and PFOS. Any facility sampled as part of the Department's Safe Drinking Water Program PFAS Sampling Plan was notified if results were over the HAL of 70 ppt. Systems with levels exceeding the HAL were instructed to conduct confirmation sampling; if confirmation samples verified levels over the HAL, the system was required to provide Tier 2 public notification (PN) consistent with existing PN requirements.

The Department has been transparent with the Safe Drinking Water Program's PFAS Sampling Plan: the sampling plan is available on the Department's website at https://files.dep.state.pa.us/Water/DrinkingWater/Perfluorinated%20Chemicals/BSDW%20PFAS%20Sampling%20Plan_Phase%201_April%202019.pdf (PA DEP, 2019) and the results are available at https://files.dep.state.pa.us/Water/DrinkingWater/Perfluorinated%20Chemicals/SamplingResults/PFAS_Sampling_Final_Results_May_2021.pdf (PA DEP, 2021c).

The rulemaking sets MCLs for PFOA at 14 ppt and PFOS at 18 ppt and, once effective, the process for implementing public notification for a violation of an MCL will follow § 109.409 (relating to tier 2 public notice—categories, timing and delivery of notice). Upon discovery of an MCL exceedance, the system shall report the circumstance to the Department within one hour of discovery. For an MCL violation, a system shall provide the Tier 2 public notice as soon as possible, but no later than 30 days after the system learns of the violation. Systems shall follow § 109.411(e)(1)(ii) and § 109.411(e)(1)(iii), which outline the specific content of a public notice for PFOA and PFOS.

56. Comment: One commentator requested that the Comment and Response Document include a key or some other method that allows public commentators to identify their comments in the document. (63)

Response: This Comment and Response Document includes commentator numbers, which correspond to the list of commentators provided in a separate document.

57. Comment: Several commentators noted that they or family members, friends, neighbors, etc., have experienced specific health conditions and expressed concern that exposure to PFAS may have played a role in those illnesses. (33, 43, 62, 71, 116, 131, 136, 138, 140)

Response: The Department acknowledges these comments and concerns about the potential health effects from PFAS exposure. PFAS are considered emerging contaminants because research is ongoing to better understand the potential impacts PFAS pose to human and animal health and the environment. PFAS are potentially linked to a number of adverse health effects, including high cholesterol, developmental effects including low birthweight, liver toxicity, decreased immune response, thyroid disease, kidney disease, ulcerative colitis and certain cancers, including testicular cancer and kidney cancer. The Drexel PFAS Advisory Group

(DPAG) reviewed pertinent literature and work across the country and independently developed recommended maximum contaminant level goals (MCLGs) based on non-cancer endpoints. The DPAG's MCLG Report discusses relevant inputs and includes a summary table for each PFAS that documents the development of the recommended MCLG (DPAG, 2021). The MCLGs for PFOA and PFOS were the basis for developing maximum contaminant levels (MCLs), as described in detail in the preamble to the proposed rulemaking (EQB, 2022). The PFOA MCL is intended to be protective of developmental effects (including neurobehavioral and skeletal effects). The PFOS MCL is intended to be protective of immunotoxicity effects (including immune suppression). It is the Department's viewpoint that it is imperative to move forward with this rulemaking at this time in the interest of public health protection.

58. **Comment:** Several commentators provided comments on issues that are outside the scope of this proposed rulemaking. Many of these comments were regarding the following topics: concern about spreading of biosolids containing PFAS and uptake of PFAS by crops; holding polluters responsible for PFAS contamination; concerns about fracking and the use of PFAS; water pollution and water standards for PFAS; improper disposal of PFAS; remediation of PFAS contaminated sites; cleanup standards for PFAS; establishing PFAS as a hazardous substance; and banning PFAS chemicals. (5, 6, 7, 17, 18, 35, 36, 38, 39, 44, 45, 46, 47, 52, 56, 57, 58, 61, 62, 63, 73, 78, 85, 86, 88, 90, 95, 105, 108, 116, 144, 146, 149, 150, 152, 168, 177, 188, 291, 297, 1050-1079, 1112, 2153, 2789)

    Response: The Department acknowledges these comments; however, they are outside the scope of this rulemaking. With this rulemaking, the Department proposes to amend Pennsylvania's safe drinking water regulations, which are promulgated under the authority of the Pennsylvania Safe Drinking Water Act (SDWA). Pennsylvania's safe drinking water regulations are only applicable to facilities that meet the definition of a public water system (PWS), which is defined in 25 Pa. Code § 109.1 as follows: "A system which provide water to the public for human consumption which has at least 15 service connections or regularly serves an average of at least 25 individuals daily at least 60 days out of the year. The term includes collection, treatment, storage and distribution facilities under control of the operator of the system and used in connection with the system. The term includes collection or pretreatment storage facilities not under control of the operator which are used in connection with the system. The term also human consumption includes water that is used for drinking, bathing and showering, cooking, dishwashing or maintaining oral hygiene."

    There are other programs within the Department with their own statutory authorities and regulatory requirements to address pollution in the environment and require corrective actions. The Department's website for program involvement on PFAS has information on coordinated efforts from the various programs https://www.dep.pa.gov/Citizens/My-Water/drinking_water/PFAS/Pages/DEP-Involvement.aspx.

    - The Bureau of Environmental Cleanup and Brownfields (BECB), Division of Site Remediation, oversees the Hazardous Sites Cleanup Program. The Hazardous Sites Cleanup Act (HSCA) provides the funding and authority to oversee remediation of known contamination sites. BECB's webpage can be accessed at https://www.dep.pa.gov/Business/Land/SiteRemediation/Pages/default.aspx.

- The Bureau of Clean Water (BCW) oversees National Pollutant Discharge Elimination System (NPDES) permitting for point source discharges, establishes water quality standards, and conducts water quality monitoring and assessments. BCW is also responsible for permitting and inspection of biosolids treatment and processing facilities. BCW's webpage can be accessed at https://www.dep.pa.gov/Business/Water/CleanWater/Pages/default.aspx.

- The Bureau of Waste Management (BWM) is responsible for permitting and inspection of hazardous, municipal, and residual waste generation, transportation, and storage, including beneficial use and disposal facilities. Involvement in the PFAS pollution cycle includes appropriately directing soil containing PFAS through the proper channels for disposal. BWM's website can be accessed at https://www.dep.pa.gov/Business/Land/Waste/Services/Pages/default.aspx.

- The Bureau of Air Quality (BAQ) oversees industrial air emissions, ambient air quality studies, air quality modeling, permitting activities, and risk assessment and risk management. BAQ's webpage can be accessed at https://www.dep.pa.gov/Business/Air/BAQ/Pages/default.aspx.

- The Office of Oil and Gas Management (OOGM) facilitates the safe exploration, development, and recovery of Pennsylvania's oil and gas reservoirs in a manner that will protect the commonwealth's natural resources and the environment. OOGM's webpage can be accessed at https://www.dep.pa.gov/Business/Energy/OilandGasPrograms/Pages/default.aspx.

Establishment of PFAS as a hazardous substance and banning PFAS chemicals would need to be considered on a national level, due to the wide variety of industries that use the chemicals. On October 18, 2021, the EPA announced its PFAS Strategic Roadmap, which is a comprehensive approach to addressing PFAS and can be accessed at https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024. According to the EPA's PFAS Strategic Roadmap, the EPA's approach includes three directives: *research* to increase understanding of PFAS; *restrict* to prevent PFAS from entering the environment; and *remediate* to cleanup PFAS contamination (US EPA, 2021b). Additionally, on October 26, 2021, EPA issued a press release announcing action to address PFAS contamination under the Resource Conservation and Recovery Act (RCRA) by initiating the process to propose adding four PFAS chemicals as RCRA Hazardous Constituents. The press release can be accessed at https://www.epa.gov/newsreleases/epa-responds-new-mexico-governor-and-acts-address-pfas-under-hazardous-waste-law.

59. Comment: Several commentators expressed general health concerns related to PFAS, as well as concerns with local water quality and associated general health concerns, including other contaminants identified in their drinking water. (39, 41, 43, 46, 52, 62, 69, 71, 75, 77, 82, 83, 86, 96, 104, 107, 108, 133, 134, 137, 140, 146, 150, 159, 167, 170, 171, 289, 293, 296, 299, 300, 301, 303, 2137, 2143, 2147, 2150, 2790)

Response: The Department acknowledges these comments; however, they are outside the scope of this rulemaking. Public water systems (PWSs) are required to provide annual water quality reports to their customers, known as the Consumer Confidence Report (CCR). The CCR contains information on monitoring conducted the previous calendar year, including detected results and whether those results are above drinking water standards.

The following are excerpts of required language from the CCR template:

> "Public water systems routinely monitor for contaminants in drinking water according to federal and state laws. All sources of drinking water are subject to potential contamination by constituents that are naturally-occurring or man-made. Those constituents can be microbes, organic or inorganic chemicals, or radioactive materials. All drinking water, including bottled water, may reasonably be expected to contain at least small amounts of some contaminants. The presence of contaminants does not necessarily indicate that the water poses a health risk. In order to assure that tap water is safe to drink, EPA prescribes regulations which limit the amount of certain contaminants in water provided by public water systems. Food & Drug Administration regulations establish limits for contaminants in bottled water which must provide the same protection for public health."
>
> "Sources of drinking water (both tap & bottled water) include rivers, lakes, streams, ponds, reservoirs, springs and wells. As water travels over the land surface or through the ground, it dissolves naturally occurring minerals (and in some cases radioactive material) and can pick up substances resulting from the presence of animals or human activity. Contaminants that may be present in source water include:
>
> - Microbial contaminants, such as viruses & bacteria, may come from sewage treatment plants, septic systems, agricultural livestock operations and wildlife.
> - Inorganic contaminants, such as salts & metals, can be naturally occurring or result from stormwater run-off, oil & gas production, mining or farming.
> - Herbicides and pesticides may come from a variety of sources such as agriculture, stormwater run-off or residential uses.
> - Organic chemical contaminants, including synthetic and volatile organic chemicals, are by-products of industrial processes and petroleum production and can also come from gas stations, stormwater run-off or septic systems.
> - Radioactive contaminants can be naturally occurring or be the result of oil & gas production or mining activities." (PA DEP, 2018a and 2018b)

PWS customers can also obtain monitoring results through the Department's Drinking Water Reporting System (DWRS) which can be found at http://www.drinkingwater.state.pa.us/dwrs/HTM/Welcome.html. Results of all monitoring conducted by PWSs and submitted to the Department are available on DWRS. DWRS is a searchable website that includes information on sources, monitoring requirements, sample results, and violation history. DWRS can be searched by individual water system (PWS ID# or name) or groups of water systems, such as by system type or size, by geographic area, etc.

60. Comment: One commentator expressed an interest in health monitoring and blood testing related to potential PFAS exposure. (140)

Response: The Department acknowledges these comments; however, they are outside the scope of this rulemaking. At the state level, the Pennsylvania Department of Health (DOH) oversees health-related concerns related to PFAS exposure. For more information, see DOH's website on PFAS projects at https://www.health.pa.gov/topics/envirohealth/Pages/PFAS.aspx.

61. Comment: Several commentators submitted comments on topics that are not relevant to the proposed rulemaking or the process of setting an MCL for PFOA or PFOS. These topics include: a copy of the Indigenous Peoples Kyoto Water Declaration; a photo of a pan with residue from evaporated water; a concern about using bottled water because of a chemical smell in water; concerns about waste management during the pandemic; a request to support a New Jersey Middle School's petition regarding unsafe drinking water in New Jersey; and an anecdote about an individual considered a whistleblower and the ramifications that followed. (95, 108, 110, 118, 153, 177)

Response: The Department acknowledges these comments; however, they are unrelated to the purpose and outside the scope of the rulemaking.

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